HAMILTON

AB 079

REPORT OF ANALYSIS No. L13764/22/JSHR

Client	Sample description *(according to declaration of Client)*
ECOCHIM-GRUP SRL OR. OTACI, STR. VOITOVICI 21 2059 CHIȘINĂU Digitally signed by Poiata Cristian Date: 2024.03.26 15:01:29 EET Reason: MoldSign Signature Location: Moldova	**DEZINFECTANT UNIVERSAL BIO-DEZ** **Lot/Batch: -** **Production date: 28.01.2022** **Expiration date: 28.01.2025** **Sampling date: -** **Sampling quantity: 2 PCS X 1000 ML** **Sample temperature: 15°C** **Reception hour: 13:30** **Responsible for sampling: CRESTINOV ALEXANDR** **Sample condition with no objections**
Sample received: **2022-02-10** Analysis completed (the date of performance of the laboratory activity): **2022-03-23** Report dated: **2022-03-23**	**Order of 2022-02-09** The samples were delivered by Client

Test	Method	Unit	Result
* Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics[1)]	PN-EN 1276:2019-12		Product diluted to 80% and 50%, shows bactericidal activity at 60 seconds, 20°C, in dirty conditions (3,0g/L bovine albumin) at reference strains: Pseudomonas aeruginosa ATCC 15442, Escherichia coli ATCC 10536, Staphylococcus aureus ATCC 6538, Enterococcus hirae ATCC 10541.
Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics[2)]	PN-EN 1650:2008+A1:2013-08		Product diluted to 80% shows fungicidal activity at 60 seconds, 20°C, in dirty conditions (3,0g/L bovine albumin) at reference strains: Candida albicans ATCC 10231 and Aspergillus brasiliensis ATCC 16404. Product diluted to 50% shows yeasticidal activity at 60 seconds, 20°C, in dirty conditions (3,0g/L bovine albumin) at reference strain: Candida albicans ATCC 10231. Product diluted to 50% does not show fungicidal activity at 60 seconds, 20°C, in dirty conditions (3,0g/L bovine albumin) at reference strain: Aspergillus brasiliensis ATCC 16404.

[1)] The results of the analysis in attachment No 1 to the report of analysis.

[2)] The results of the analysis in attachment No 2 to the report of analysis.

THE END OF THE REPORT

Authorized by: Sylwia Ziętek, Analyst Specialist, Cosmetics Microbiology Laboratory
Approved by: Hanna Wachowska, Laboratory Director *(Approved with electronic signature)*

Laboratory: Tychy 43-100, Goździków 1

* Test method accredited; # Test performed by external provider

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TESTING LABORATORY
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ENCLOSURE No. 1 TO REPORT OF ANALYSIS NO. L13764/22/JSHR

A) IDENTIFICATION OF THE SAMPLE	
Name of the product	**DEZINFECTANT UNIVERSAL BIO-DEZ** Lot/Batch: - Production date: 28.01.2022 Expiration date: 28.01.2025 Sampling date: - Sampling quantity: 2 PCS X 1000 ML Sample temperature: 15°C Reception hour: 13:30 Responsible for sampling: CRESTINOV ALEXANDR
Active substance	Ethyl alcool 72-76% CAS 64-17-5 CE 200-578-6 Benzalkonium chloride 0,024-0,029% CAS 68424-85-1 CE 270-325-2 Methylthioninium chloride 0,00024% CAS 61-73-4 CE 200-515-2
Aspect of the received product	Blue liquid in plastic clear container
B) TEST METHOD AND ITS VALIDATION-	
Method	**PN-EN 1276:2019-12** **Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas – Test method and requirements (phase 2, step 1)**
Neutralizer	Sodium thiosulphate 3 g/l, polysorbate 80 30 g/l, lecithin 3 g/l
C) EXPERIMENTAL CONDITIONS	
Product test concentrations (%V/V)	0,01%, 50%, 80%
Aspect of product dilutions	80% and 50% blueish; 0,01% colourless
Test temperature	20˚C
Contact time	60 seconds
Interfering substance	Dirty conditions: 3,0 g/l bovine albumin
Product diluent	Sterile hard water
Stability of the mixture (interfering substance and diluted product in sterile hard water)	Stable
Temperature of incubation	37±1˚C
Identification of the bacterial and fungal strains used:	*Escherichia coli ATCC* 10536 *Pseudomonas aeruginosa* ATCC 15442 *Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541
Special remarks	All controls and validation were between the basic limits. At least one concentration showed a log reduction lower than 5 log. At least one concentration showed a log reduction higher than 5 log. No precipitate formed during the test procedure (the test mixtures were homogeneous).

Date: 23.03.2022

Authorized by: Sylwia Ziętek, Analyst Specialist, Cosmetics Microbiology Laboratory
Approved by: Hanna Wachowska, Laboratory Director (Approved with qualified electronic signature)

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ENCLOSURE No. 1 TO REPORT OF ANALYSIS NO. L13764/22/JSHR

TABLE 1. RESULTS OF THE TEST FOR BACTERICIDAL ACTIWITY OF THE PRODUCT

INTERFERING SUBSTANCE: 3,0 g/l BOVINE ALBUMIN - DIRTY CONDITIONS
CONTACT TIME: 60 seconds
TEST TEMPERATURE: 20˚c
PRODUCT TEST CONCENTRATIONS: 0,01%, 50%, 80%

TEST ORGANISM	VALIDATION VALIDATION SUSPENSION				VALIDATION A			VALIDATION B			VALIDATION C		
	VC1	VC2	Nv	Nvo	VC1	VC2	A	VC1	VC2	B	VC1	VC1	C
Escherichia coli ATCC 10536	115	119	1170	117	88	85	87	77	71	74	63	66	65
***Staphylococcus aures* ATCC 6538**	121	128	1245	125	91	82	87	69	66	68	65	62	64
***Pseudomonas aeruginosa* ATCC 15442**	114	106	1100	110	77	76	77	63	61	62	55	59	57
***Enetrococcus hirae* ATCC 10541**	132	141	1365	137	85	81	83	71	75	73	68	71	70
criteria	**300 ≤ Nv ≤ 1600**		**30 ≤ Nv0 ≤ 160**		**A ≥ 0,5*N_{v0} acceptable**			**B ≥ 0,5*N_{v0} acceptable**			**C ≥ 0,5*N_{v0} acceptable**		

TEST ORGANISM	TEST SUSPENSION							
	-6	-6	-7	-7	N	lgN	N_0	**lgN_0**
Escherichia coli ATCC 10536	192	199	18	17	1,9E+08	8,29	1,9E+07	7,29
***Staphylococcus aures* ATCC 6538**	169	166	15	16	1,7E+08	8,22	1,7E+07	7,22
***Pseudomonas aeruginosa* ATCC 15442**	184	188	18	19	1,9E+08	8,27	1,9E+07	7,27
***Enetrococcus hirae* ATCC 10541**	174	182	17	18	1,8E+08	8,25	1,8E+07	7,25
criteria	**$1,5*10^8 \leq N \leq 5*10^8$**		**8,17 ≤ logN ≤ 8,70**		**$1,5*107 \leq N_0 \leq 5*107$**		**7,17 ≤ logN_0 ≤ 7,70**	

TEST ORGANISM		0,01%					50%					80%				
	N	VC1	VC2	Na	lg Na	**lg R**	VC1	VC2	Na	lg Na	**lg R**	VC1	VC2	Na	lg Na	**lg R**
Escherichia coli ATCC 10536	1,9E+08	>330	>330	>3300	>3,52	**<3,75**	0	0	<140	<2,15	**>5,14**	0	0	<140	<2,15	**>5,14**
***Staphylococcus aures* ATCC 6538**	1,7E+08	>330	>330	>3300	>3,52	**<3,67**	0	0	<140	<2,15	**>5,07**	0	0	<140	<2,15	**>5,07**
***Pseudomonas aeruginosa* ATCC 15442**	1,9E+08	>330	>330	>3300	>3,52	**<3,77**	0	0	<140	<2,15	**>5,12**	0	0	<140	<2,15	**>5,12**
***Enetrococcus hirae* ATCC 10541**	1,8E+08	>330	>330	>3300	>3,52	**<3,74**	16	17	165	2,22	**5,03**	0	0	<140	<2,15	**>5,10**
criteria	**lg R ≥ 5**															

Vc- number of cfu/ ml (one or two plates)
Nv- validation suspension
Nvo- Nv/10
A- validation of test conditions
B- neutralizer validation
C- validation dilution-neutralization
N- test suspension
No- N/10
Na- number of microorganisms cfu/ml in the test suspension
R- reduction No/Na
lg- logarithm 10

Date: 23.03.2022

Authorized by: Sylwia Ziętek, Analyst Specialist, Cosmetics Microbiology Laboratory
Approved by: Hanna Wachowska, Laboratory Director (Approved with qualified electronic signature)

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HAMILTON

ENCLOSURE No. 2 TO REPORT OF ANALYSIS NO. L13764/22/JSHR

A) IDENTIFICATION OF THE SAMPLE	
Name of the product	**DEZINFECTANT UNIVERSAL BIO-DEZ** Lot/Batch: - Production date: 28.01.2022 Expiration date: 28.01.2025 Sampling date: - Sampling quantity: 2 PCS X 1000 ML Sample temperature: 15°C Reception hour: 13:30 Responsible for sampling: CRESTINOV ALEXANDR
Active substance	Ethyl alcool 72-76% CAS 64-17-5 CE 200-578-6 Benzalkonium chloride 0,024-0,029% CAS 68424-85-1 CE 270-325-2 Methylthioninium chloride 0,00024% CAS 61-73-4 CE 200-515-2
Aspect of the received product	Blue liquid in plastic clear container
B) TEST METHOD AND ITS VALIDATION	
	PN-EN 1650:2019-12 – Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas – Test method and requirements (phase 2, step 1)
Neutralizer	Polisorbate 80- 30 g/l, saponin- 30 g/l, lecithin 3g/l
C) EXPERIMENTAL CONDITIONS	
Product test concentrations	0,01%, 50%, 80%
Aspect of product dilutions	80% and 50% blueish; 0,01% colourless
Test temperature	20˚C
Contact time	60 seconds
Interfering substances	Dirty conditions: 3,0 g/l bovine albumin
Product diluent	Sterile hard water
Stability of the mixture (interfering substance and diluted product in sterile hard water)	Stable
Temperature of incubation	30°C ± 1°C
Identification of the bacterial and fungal strains used	*Candida albicans* ATCC 10231 *Aspergillus brasiliensis* ATCC 16404
Special remarks	All controls and validation were between the basic limits. At least one concentration showed a log reduction lower than 5 log. At least one concentration showed a log reduction higher than 5 log. No precipitate formed during the test procedure (the test mixtures were homogeneous).

Date: 23.03.2022

Authorized by: Sylwia Ziętek, Analyst Specialist, Cosmetics Microbiology Laboratory
Approved by: Hanna Wachowska, Laboratory Director (Approved with qualified electronic signature)

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ENCLOSURE No. 2 TO REPORT OF ANALYSIS NO. L13764/22/JSHR

TABLE 1. RESULTS OF THE TEST FOR BACTERICIDAL ACTIWITY OF THE PRODUCT

INTERFERING SUBSTANCE: 3,0 g/l BOVINE ALBUMIN - DIRTY CONDITIONS
CONTACT TIME: 60 seconds
TEST TEMPERATURE: 20°C
PRODUCT TEST CONCENTRATIONS: 0,01%, 50%, 80%

TEST ORGANISM	VALIDATION VALIDATION SUSPENSION				VALIDATION A			VALIDATION B			VALIDATION C		
	VC1	VC2	Nv	Nv_0	VC1	VC2	A	VC1	VC2	B	VC1	VC1	C
***Candida albicans* ATCC 10231**	126	121	1235	124	92	85	89	79	75	77	73	66	70
***Aspergillus brasiliensis* ATCC 16404**	115	118	1165	117	88	83	86	81	72	77	71	78	75
criteria	**$300<N_v<1600$ $30<N_{v0}<160$ acceptable**				**$A \geq 0,5*N_{v0}$ acceptable**			**$B \geq 0,5*N_{v0}$ acceptable**			**$C \geq 0,5*N_{v0}$ acceptable**		

TEST ORGANISM	TEST SUSPENSION							
	-5	-5	-6	-6	N	lg N	N_0	lg N_0
***Candida albicans* ATCC 10231**	189	192	18	19	1,9E+07	7,28	1,9E+06	6,28
***Aspergillus brasiliensis* ATCC 16404**	>165	>165	21	22	2,2E+07	7,33	2,2E+06	6,33
criteria	**$1,5*10^7 \leq N \leq 5*10^7$ acceptable** **$7,17 \leq lg\ N \leq 7,70$ acceptable**					**$1,5*10^6 \leq N_0 \leq 5*10^6$ acceptable** **$6,17 \leq lg\ N_0 \leq 6,70$ acceptable**		

TEST ORGANISM	N	0,01%					50%					80%				
		VC1	VC2	Na	lg Na	**lg R**	VC1	VC2	Na	lg Na	**lg R**	VC1	VC2	Na	lg Na	**lg R**
***Candida albicans* ATCC 10231**	1,9E+07	>330	>330	>3300	>3,52	**<2,76**	0	0	<140	<2,15	**>4,13**	0	0	<140	<2,15	**>4,13**
***Aspergillus brasiliensis* ATCC 16404**	2,2E+07	>165	>165	>1650	>3,22	**<3,11**	>165	>165	>1650	>3,22	**<3,11**	2	5	<140	<2,15	**>4,18**
criteria	**lg R ≥ 4**															

Vc- number of cfu/ ml (one or two plates)
Nv- validation suspension
Nvo- Nv/10
A- validation of test conditions
B- neutralizer validation
C- validation dilution-neutralization
N- test suspension
No- N/10
Na- number of microorganisms cfu/ml in the test suspension
R- reduction No/Na
lg- logarithm 10

Date: 23.03.2022

Authorized by: Sylwia Ziętek, Analyst Specialist, Cosmetics Microbiology Laboratory
Approved by: Hanna Wachowska, Laboratory Director (Approved with qualified electronic signature)

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HAMILTON

AB 079

REPORT OF ANALYSIS No. 136987/21/JSHR/Z2

Replaces Report of Analysis No. 136987/21/JSHR of 2021-04-14

Client	Sample description *(according to declaration of Client)*
ECOCHIM-GRUP SRL OR. OTACI, STR. VOITOVICI 21 2059 CHIȘINĂU	**DEZINFECTANT UNIVERSAL "BIO-DEZ"** **Sample quantity: 2 pcs x 1 L** **Production date: 26.01.2021** **Expiration date: 26.01.2024** **Sampling date: 22.02.2021** **Sample temperature: 15°C** **Reception hour: 15:00** **Responsible for sampling: Crestinov Alexandr**
Sample received: **2021-03-18**	**Sample condition with no objections**
Analysis completed (the date of performance of the laboratory activity): **2021-04-14**	**Order of 2021-03-09**
Report dated: **2021-07-27**	The samples were delivered by Client

Test	Method	Unit	Result
* Chemical disinfectants and antiseptics - Hygienic handrub - Test method and requirements (phase 2, step 2)[1)]	PN-EN 1500:2013-07		The preparation has bactericidal effect against transient microorganisms used in the hygienic procedure of hand disinfection - a single rubbing of 3ml of the preparation for 60 seconds.

[1)] The results of the analysis in attachment No 1 to the report of analysis.

Identification of the change: test result

THE END OF THE REPORT

Authorized by:
Approved by: Hanna Wachowska, Laboratory Director *(Approved with electronic signature)*

Laboratory: Tychy 43-100, Goździków 1

* Test method accredited; # Test performed by external provider

J.S. HAMILTON POLAND Sp. z o.o.
TESTING LABORATORY
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ENCLOSURE No. 1 TO REPORT OF ANALYSIS NO. 136987/21/JSHR/Z2

A) IDENTYFICATION OF THE SAMPLE:	
Name of the product	**DEZINFECTANT UNIVERSAL "BIO-DEZ"** Sample quantity: 2 pcs x 1 L Production date: 26.01.2021 Expiration date: 26.01.2024 Sampling date: 22.02.2021 Sample temperature: 15°C Reception hour: 15:00 Responsible for sampling: Crestinov Alexandr
The active substance	Ethyl alcohol 72-76% CAS 64-17-5 CE 200-578-6 Benzalkonium chloride 0,024-0,029% CAS 68424-85-1 CE 270-325-2 Methylthioninium chloride 0,00024% CAS 61-73-4 and 200-515-2
B) TEST METHOD :	
Method	**EN 1500:2013 Chemical disinfectants and antiseptics - Hygienic handrub - Test method and requirements (*phase 2, step 2*)**
Neutralizer	Polysorbate 80 30 g/l, saponine 30g/l, histidine 1g/l, cysteine 1g/l
C) EXPERIMENTAL CONDITIONS:	
Product test concentrations (%V/V)	100%
Test temperature	20°C
Contact time	3ml of the preparation for 60s
Incubation temperature	36±1 °C
Test-organism	*E. coli* K12 NCTC 10538

Date: 27.07.2021

Authorized by: Daria Depa, Senior Specialist Analyst, Cosmetics Microbiology Laboratory
Approved by: Hanna Wachowska, Laboratory Director *(Approved with qualified electronic signature)*

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ENCLOSURE No. 1 TO REPORT OF ANALYSIS NO. 136987/21/JSHR/Z2

Table 1. PROCEDURE FOR REFERENCE HYGIENIC HANDRUB

PRODUCT: Standard 2-propanol 60% (V/V)
TEST ORGANISM: *E. coli* K12 NCTC 10538
NUMBER IN CONTAMINATION FLUID: 2,4 x 10^8 cfu/ml

volunteer		number of cfu per plate from dilution 10x							
	Hand	prevalues			postvalues				Reduction
Nr	left/right	x10^{-4}	x10^{-5}	log x	x10^{0}	x10^{-1}	x 10^{-2}	log y	log z
	l	288	29		61	7	0		
1	r	247	22	6,42	33	3	0	1,65	4,77
	l	167	17		51	5	0		
2	r	291	28	5,81	36	4	0	1,63	4,18
	l	175	11		42	5	0		
3	r	275	25	6,33	29	2	0	1,54	4,79
	l	220	21		30	3	0		
4	r	192	19	6,31	68	6	0	1,65	4,66
	l	164	15		37	3	0		
5	r	301	33	6,35	52	5	0	1,64	4,71
	l	200	20		23	2	0		
6	r	198	18	6,30	37	4	0	1,46	4,83
	l	287	22		60	6	0		
7	r	288	29	6,45	42	5	0	1,70	4,75
	l	298	28		31	4	0		
8	r	213	21	6,40	58	5	0	1,63	4,77
	l	283	23		34	3	0		
9	r	311	33	5,96	51	5	0	1,62	4,34
	l	313	32		53	6	0		
10	r	251	25	6,45	36	4	0	1,65	4,80
	l	175	18		54	5	0		
11	r	295	22	6,35	47	3	0	1,69	4,66
	l	183	19		72	7	0		
12	r	171	17	5,74	36	4	0	1,71	4,03
	l	206	22		29	2	0		
13	r	317	33	6,41	49	5	0	1,57	4,84
	l	295	28		55	6	0		
14	r	279	25	6,45	64	7	0	1,78	4,68
	l	248	22		72	7	0		
15	r	256	26	6,40	66	6	0	1,84	4,56
	l	301	31		46	5	0		
16	r	261	26	6,45	27	3	0	1,55	4,90
	l	259	24		41	4	0		
17	r	271	28	6,42	22	1	0	1,47	4,96
	l	259	22		61	6	0		
18	r	288	23	6,43	33	3	0	1,65	4,78
	l	223	21		35	4	0		
19	r	205	20	6,33	45	5	0	1,60	4,72
	l	297	28		54	6	0		
20	r	257	24	5,90	28	3	0	1,59	4,31
$x_{śr}$				6,28				1,63	4,65
s				0,23				0,09	0,25

log x-logarithm of the average value of the initial left and right hand
log y-logarithm of the average value of the final left and right hand
log z-logarithm reduction
x śr- overall average of log x, log y, log z

Date: 27.07.2021

Authorized by: Daria Depa, Senior Specialist Analyst, Cosmetics Microbiology Laboratory
Approved by: Hanna Wachowska, Laboratory Director *(Approved with qualified electronic signature)*

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ENCLOSURE No. 1 TO REPORT OF ANALYSIS NO. 136987/21/JSHR/Z2

Table 2. HYGIENIC HANDRUB PROCEDURE WITH THE PRODUCT

PRODUCT P 136987/21/JSHR
TEST ORGANISM: *E. coli* K12 NCTC 10538
NUMBER IN CONTAMINATION FLUID: 2,4 x 10^8 cfu/ml

volunteer		number of cfu per plate from dilution 10x							Reduction
	Hand	prevalues			postvalues				
Nr	left/right	x10^{-4}	x10^{-5}	log x	x10^{0}	x10^{-1}	x 10^{-2}	log y	log z
	l	132	14		103	11	1		
1	r	224	21	6,24	92	9	0	1,98	4,26
	l	>330	125		89	7	0		
2	r	304	31	6,27	78	4	0	1,68	4,59
	l	144	15		97	9	0		
3	r	132	11	6,14	78	5	0	1,93	4,21
	l	328	34		87	8	0		
4	r	>330	85	6,20	99	9	0	1,89	4,32
	l	164	11		116	11	2		
5	r	132	12	6,16	99	8	0	2,03	4,13
	l	>330	121		61	3	0		
6	r	320	32	6,27	83	9	0	1,67	4,60
	l	328	33		61	4	0		
7	r	288	29	6,49	71	7	0	1,81	4,68
	l	>330	58		91	9	0		
8	r	>330	22	5,51	72	6	0	1,82	3,69
	l	336	36		79	8	0		
9	r	>330	21	5,90	106	12	2	1,96	3,94
	l	296	28		74	7	0		
10	r	>330	41	6,02	85	9	0	1,90	4,12
	l	228	21		93	8	0		
11	r	104	11	6,19	80	5	0	1,93	4,26
	l	>330	48		107	11	1		
12	r	200	20	5,97	94	9	0	1,98	4,00
	l	248	25		112	14	2		
13	r	212	22	6,36	113	11	1	2,06	4,31
	l	>330	48		89	8	0		
14	r	255	22	6,02	91	9	0	1,95	4,07
	l	278	28		99	7	0		
15	r	169	17	6,34	67	6	0	1,77	4,57
	l	178	11		104	11	1		
16	r	255	25	6,32	69	7	0	1,93	4,39
	l	274	28		79	8	0		
17	r	231	24	6,40	107	12	2	1,97	4,44
	l	225	22		92	9	0		
18	r	183	19	6,31	66	7	0	1,89	4,42
	l	199	17		53	5	0		
19	r	252	23	6,35	89	8	0	1,83	4,51
	l	266	22		97	9	0		
20	r	231	21	6,39	68	7	0	1,91	4,48
$x_{śr}$				6,19				1,89	4,30
s				0,22				0,10	0,25

log x-logarithm of the average value of the initial left and right hand
log y-logarithm of the average value of the final left and right hand
log z-logarithm reduction
x śr- overall average of log x, log y, log z

Date: 27.07.2021

Authorized by: Daria Depa, Senior Specialist Analyst, Cosmetics Microbiology Laboratory
Approved by: Hanna Wachowska, Laboratory Director *(Approved with qualified electronic signature)*

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ENCLOSURE No. 1 TO REPORT OF ANALYSIS NO. 136987/21/JSHR/Z2

Table 3. LIST OF COMPUTED IG VALUES AND IG REDUCTIONS

volunteer		R 2-propanol 60% (V/V)			P		
Nr		log x	log y	log z	log x	log y	log z
1	R-P	6,42	1,65	4,77	6,24	1,99	4,25
2	R-P	5,81	1,63	4,18	6,27	1,91	4,36
3	R-P	6,33	1,54	4,79	6,14	1,93	4,21
4	R-P	6,31	1,65	4,66	6,20	1,96	4,24
5	R-P	6,35	1,64	4,71	6,16	2,03	4,13
6	P-R	6,30	1,46	4,83	6,27	1,84	4,43
7	P-R	6,45	1,70	4,75	6,49	1,81	4,68
8	P-R	6,40	1,63	4,77	5,51	1,90	3,61
9	P-R	5,96	1,62	4,34	5,90	1,96	3,94
10	P-R	6,45	1,65	4,80	6,02	1,90	4,12
11	R-P	6,35	1,69	4,66	6,19	1,93	4,26
12	R-P	5,74	1,71	4,03	5,97	2,00	3,97
13	R-P	6,41	1,57	4,84	6,36	2,06	4,31
14	R-P	6,45	1,78	4,68	6,02	1,95	4,07
15	R-P	6,40	1,84	4,56	6,34	1,90	4,43
16	P-R	6,45	1,55	4,90	6,32	1,93	4,39
17	P-R	6,42	1,47	4,96	6,40	1,97	4,44
18	P-R	6,43	1,65	4,78	6,31	1,89	4,42
19	P-R	6,33	1,60	4,72	6,35	1,83	4,51
20	P-R	5,90	1,59	4,31	6,39	1,91	4,48
X_{20}		**6,28**	1,63	4,65	**6,19**	1,93	4,26
X10(R-P)		6,26	1,67	**4,59**	6,19	1,97	**4,22**
X10 (P-R)		6,31	1,59	**4,72**	6,20	1,90	**4,30**

Criteria:
Rs (R-P) = 4,59-4,22=0,37
Rs (P-R)= 4,72-4,30=0,42
Abs= 0,37-0,42=-0,05<2
logx(R)= 6,28>5
logx(P)= 6,19>5
logz (P), logz (R) >3

Validation conditions of neutralizer and methods have been satisfied

Date: 27.07.2021

Authorized by: Daria Depa, Senior Specialist Analyst, Cosmetics Microbiology Laboratory
Approved by: Hanna Wachowska, Laboratory Director *(Approved with qualified electronic signature)*

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ENCLOSURE No. 1 TO REPORT OF ANALYSIS NO. 136987/21/JSHR/Z2

Table 4. COMPUTATION OF INDIVIDUAL DIFFERENCES OF lg R-P

volunteer	log RF		difference	difference	
	R	P	R-P	high to low	Range +/-
1	4,77	4,25	0,52	1,16	1
2	4,18	4,36	-0,18	0,68	2
3	4,79	4,21	0,59	0,61	3
4	4,66	4,24	0,42	0,59	4
5	4,71	4,13	0,58	0,58	5
6	4,83	4,43	0,40	0,53	6
7	4,75	4,68	0,07	0,52	7
8	4,77	3,61	1,16	0,52	8
9	4,34	3,94	0,40	0,51	9
10	4,80	4,12	0,68	0,42	10
11	4,66	4,26	0,40	0,40	11
12	4,03	3,97	0,06	0,40	12
13	4,84	4,31	0,53	0,40	13
14	4,68	4,07	0,61	0,36	14
15	4,56	4,43	0,13	0,21	15
16	4,90	4,39	0,51	0,13	16
17	4,96	4,44	0,52	0,07	17
18	4,78	4,42	0,36	0,06	18
19	4,72	4,51	0,21	-0,17	-19
20	4,31	4,48	-0,17	-0,18	-20
sum of ranks (+): 171					
sum of ranks (-): 39					

Table 5. SORTING OF INDIVIDUAL DIFFERENCES AND COMPUTATION FOR HODGES-LEHMANN 97,5% UPPER CONFIDENCE LIMITS FOR THE DIFFERENCE IN lg BETWEEN R-P

		1,16	0,68	0,61	0,59	0,58	0,53	0,52	0,52	0,51
1	1,16	1,16								
2	0,68	0,92	0,68							
3	0,61	0,89	0,65	0,61						
4	0,59	0,87	0,63	0,60	0,59					
5	0,58	0,87	0,63	0,59	0,58	0,58				
6	0,53	0,85	0,61	0,57	0,56	0,55	0,53			
7	0,52	0,84	0,60	0,57	0,56	**0,55**	0,53	-0,52		
8	0,52	0,84	0,60	0,56	0,55	0,55	0,53	-0,52	-0,52	
9	0,51	0,83	0,59	0,56	0,55	0,54	0,52	-0,52	-0,51	-0,51
10	0,42	0,79	0,55	0,52	0,50	0,50	0,48	-0,47	-0,47	-0,21
11	0,40	0,78	0,54	0,51	0,49	0,49	0,47	-0,46	-0,46	-0,20
12	0,40	0,78	0,54	0,51	0,49	0,49	0,47	-0,46	-0,46	
13	0,40	0,78	0,54	0,50	0,49	0,49	0,47	-0,46		
14	0,36	0,76	0,52	0,49	0,47	0,47	0,45			
15	0,21	0,69	0,45	0,41	0,40	0,39				
16	0,13	0,65	0,41	0,37	0,36					
17	0,07	0,62	0,38	0,34						
18	0,06	0,61	0,37							
19	-0,17	0,50								
20	-0,18									

Date: 27.07.2021

Authorized by: Daria Depa, Senior Specialist Analyst, Cosmetics Microbiology Laboratory
Approved by: Hanna Wachowska, Laboratory Director *(Approved with qualified electronic signature)*

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Table 6. WILCOXON'S TMATCHED PAIRS SIGNED-RANKS TEST:
CRITICAL VALUES LESS WITH RANG SUM (+) OR (-) AT DIFFERENT LEVELS OF SIGNIFICANCE

n	one-sided level of significance		
	0,05	**0,025**	0,01
18	47	**40**	32
19	53	**46**	27
20	60	**52**	43
21	68	**59**	49
22	75	**66**	56

For the designated level of significance 0,025 for n=20 the value read from the table 6 is 52.
Hence c = 52+1 =53.
For the distribution of 53 Table 5 assigns a value of 0,55 which is less than the agreed inferiority margin of 0,6.
Therefore, the hypothesis of inferiority of PP compared to the reference RP is rejected.
The test preparation (PP) is non-inferior to RP.

Date: 27.07.2021

Authorized by: Daria Depa, Senior Specialist Analyst, Cosmetics Microbiology Laboratory
Approved by: Hanna Wachowska, Laboratory Director *(Approved with qualified electronic signature)*

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HAMILTON ROMANIA

RAPORT DE INCERCARE NR. 79165/22/ROBCH/Z1

Inlocuieste Raportul de Incercare Nr. 79165/22/ROBCH din 07.03.2022

Client	Numărul eșantionului:
ECOCHIM-GRUP SRL OR. OTACI, STR. VOITOVICI 21 2059 CHIȘINĂU	Sample number Descriere obiect de incercat (conform cu declaratia Clientului) Dezinfectant Universal "Bio-Dez" Lot/Batch: - Production date: - Expiration date: 18.02.2025 Sampling date: 18.02.2022 Sampling quantity: 1x 500ml Sample temperature: 20°C Reception hour: 12:30 Responsible for sampling: Crestinov Alexandr Sample condition with no objections
Data primirii obiectului de incercat: 07.03.2022	
Data finalizarii incercarii: 08.09.2022	Comanda din 07.03.2022
Data eliberarii raportului: 08.09.2022	Probele au fost prelevate si livrate de catre Client.

Parametrii de testare	Metoda de testare	Unitate de masura	Rezultat
# * Chemical disinfectants and antiseptics. Surgical hand disinfection. Test method and requirements (phase 2, step 2)	EN 12791:2016+A1:2017	-	Test method performed by the subcontractor; the results are taken in full from the test report No S68/2022-1, issued by the subcontractor. The results of the analysis are listed starting with enclosure No1 to report of analysis.

Elaborat de: Mariana Ilinca, Sef Laborator Microbiologie
Autorizat de: Mariana Ilinca, Sef Laborator Microbiologie
Aprobat de catre: Alina-Roxana Mihai, General Manager (Aprobat cu semnatura electronica)

Laborator: Bucuresti 041914, sos. Berceni nr.8

* Metoda de testare acreditata # Test efectuat de catre subcontractor
ø Incercari neacreditate

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Autorizatie A.N.S.V.S.A. nr. 115 din 18.06.2018

ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 79165/22/ROBCH

A) IDENTYFICATION OF THE SAMPLE	
Name of the product/Details about the product	**Dezinfectant Universal "Bio-Dez"** Date of manufacture: 18.02.2022 Manufacturer: Ecochim-Grup SRL, Petricani St 21/3, Chișinău 2059, Moldavsko Incoming date: 7.3.2022 Storing conditions: room temperature, dark area. Subject of testing: Surgical handrub - immediate effect Active ingredients: CAS: 68424-85- Alkyldimethylbenzylamoniumchloride 0.029% CAS: 64-17-5 Ethyl alcohol 73.0%
B) TEST METHOD	
Performed in accredited subcontracted partner laboratory: Scope of Accreditation No. 1273 Determination of surgical hand disinfection (EN 12791:2016+A1:2017) of the product **Dezinfectant Universal "Bio-Dez"**	Testing of disinfecting efficiency of chemical disinfecting and antiseptic agents on carriers SOP-M-19-00 (EN 12791:2016+A1:2017)
C) Description: Testing the efficacy of chemical disinfectants and antiseptics	
Sampling date:	18.2.2022
Sample delivered:	7.3.2022
Testing date:	16.8. - 31.8.2022
D) EXPERIMENTAL CONDITIONS	
Effect:	immediate effect
Period of analysis:	16.08.2022 - 31.08.2022
Test temperature:	20 °C ± 1 °C
Test method:	dilution neutralization method
Appearance of the product:	Blue liquid
The test concentration:	100%
The volume of the product:	2 x 7 ml
The application time:	2 x 45 s
Procedure:	handrub
The soap:	soft soap from linseed oil
Reference item:	CAS 71-23-8 1-propanol p.a., 60% (V/V)
The volume of the reference propan- -1-ol used per person: 2 x 3 ml, according to reference surgical hand disinfection procedure, the total application volume is 6 ml	
The application time:	2 x 1.5 min, according to reference surgical hand disinfection procedure, the total application time is 3 min
Neutralization medium:	Dey-Engley Neutralizing Broth M 1062
Surgical hand disinfection procedure with product:	handrub procedure, immediate effect
Requirements:	The mean reduction for immediate effect of a product shall at least be not inferior to that achieved by a specified reference product (60% volume concentration of propan-1-ol). To demonstrate additionally a "sustained effect", the mean reduction for the 3 h effect of a product shall be superior to that achieved by the reference product
Test procedure:	1. Determination of the presence of microorganisms in the product 2. Determination of the prevalue – number of cfu sampled immediately before treatment from the hand 3. Determination of the postvalue – number of cfu sampled after

ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 79165/22/ROBCH

	treatment from the hand 4. Expression and interpretation of results - reduction factor – ratio of prevalue and postvalue, generally expressed by decimal logarithms
The standard:	EN 12791:2016+A1:2017 Chemical disinfectants and antiseptics – Surgical hand disinfection – Test method and requirements (phase 2/step 2) November 2017

The number of CFU in the tested product: 0 CFU/ml

Testing the efficacy of chemical disinfectant **L21229/22/JSHR** *on Pseudomonas aeruginosa* ATCC 15442

Test suspensions

N	V1	V2	lgN	lgN_0
10^{-6}	192	170		
10^{-7}	27	15	8,26	7,26
		$\Phi = 1,84x10^8$	*8,17* ≤ lgN ≤ *8,7*	*7,17* ≤ lgN_0 ≤ *7,7*

Verification of methodology

Validation of suspension (N_{V0})		Method valid.(C), conditions: 80 %, 90 s, distilled water, 20°C	
V_{c1}	31	V_{c1}	29
V_{c2}	60	V_{c2}	55
30 < 45,5 < 160		42 > 0,5 Nvo	

Testing the efficacy of chemical disinfectant **L21229/22/JSHR** *on Staphylococcus aureus* ATCC 6538

Test suspensions

N	V1	V2	lgN	lgN_0
10^{-6}	304	252		
10^{-7}	20	33	8,44	7,44
		$\Phi = 2,77x10^8$	*8,17* < lgN < *8,7*	*7,17* < lgN_0 < *7,7*

Verification of methodology

Validation of suspension (N_{V0})		Method valid.(C), conditions: 80 %, 90 s, distilled water, 20°C	
V_{c1}	69	V_{c1}	72
V_{c2}	53	V_{c2}	42
30 < 61 < 160		57 > 0,5 Nvo	

Testing the efficacy of chemical disinfectant **L21229/22/JSHR** *on Enterococcus hirae* ATCC 10541

Test suspensions

N	V1	V2	lgN	lgN_0
10^{-6}	166	192		
10^{-7}	18	21	8,26	7,26
		$\Phi = 1,8x10^8$	*8,17* ≤ lgN ≤ *8,7*	*7,17* ≤ lgN_0 ≤ *7,7*

Verification of methodology

Validation of suspension (N_{V0})		Method valid.(C), conditions: 80 %, 90 s, distilled water, 20°C	
V_{c1}	52	V_{c1}	46
V_{c2}	40	V_{c2}	42
30 < 46 < 160		44 > 0,5 Nvo	

ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 79165/22/ROBCH

Testing the efficacy of chemical disinfectant **L21229/22/JSHR** *on Escherichia coli K 12* NCTC 10538

Test suspensions

N	V1	V2	lgN	lgN$_0$
10^{-6}	>330	>330		
10^{-7}	49	33	8,61	7,61
		$\Phi = 4,1x10^{8}$	*8,17* < lgN < *8,7*	*7,17* < lgN$_0$ < *7,7*

Verification of methodology

Validation of suspension (Nv0)		Method valid.(C), conditions: 80 %, 90 s, distilled water, 20°C	
Vc1	113	Vc1	103
Vc2	103	Vc2	110
30 < 108 < 160		106,5 > 0,5 Nvo	

Testing the efficacy of chemical disinfectant **L21229/22/JSHR** *on Candida albicans* ATCC 10231

Test suspensions

N	V1	V2	lgN	lgN$_0$
10^{-5}	155	144		
10^{-6}	17	15	7,18	6,18
		$\Phi = 1,5x10^{7}$	*7,17* ≤ lgN ≤ *7,7*	*7,17* ≤ lgN$_0$ ≤ *7,7*

Verification of methodology

Validation of suspension (Nv0)		Method valid.(C), conditions: 80 %, 90 s, distilled water, 20°C	
Vc1	41	Vc1	21
Vc2	34	Vc2	28
30 < 37,5 < 160		24,5 > 0,5 Nvo	

Note: Vc = value is the number of cfu per ml, Φ = average Vc1 a Vc2 (1. + 2. duplicate Vc values), N = the number of cfu/ml of the bacterial test suspension, Nv0 = the number of cfu/ml of the bacterial test suspension at the beginning of the contact time = 0, C = the number of surviving bacteria per ml in control tests

Acceptance criteria for test results:

Only if the results of the test procedure fulfil the following requirements, they shall be accepted for further evaluation, otherwise the test shall be repeated:

a) A complete set of results from at least 23, but maximum 28 volunteers shall be available. All complete sets of results shall be used for further evaluation.

b) The overall means of the lg prevalues for RP and PP shall be both at least 3,50.

c) The absolute difference of mean differences between lg reductions of RP and PP of group RP → PP and group PP → RP shall be less than 2,00

d) All quotients of weighted mean counts between 5 and 15.

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Date: 08.09.2022
Authorized by: Mariana Ilinca, Manager of Microbiological laboratory
Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 79165/22/ROBCH

Conclusion:

The acceptance criteria for the test results were met.
From table in EN 12791:2016+A1:2017 of critical values for Wilcoxon's matched-pairs signed-ranks test the entry for n = 24 and a one sided 0,025 level of significance, the critical value of 81 is found. **Hence c = 81 +1 = 82**. The pairwise differences are sorted in descending order. **The 82nd value is 0,59.** Hence the Hodges-Lehmann upper one sided 97,5% confidence limit for the difference in lg Rs between RP and PP is 0,59, which is less than the agreed inferiority margin of 0,75. Therefore the hypothesis of inferiority of PP is rejected and it can be concluded that the test preparation PP is non-inferior to RP.

The tested product:	**Dezinfectant Universal "Bio-Dez"**
Batch number:	Not specified
Standard:	EN 12791:2016+A1:2017
Test method:	dilution neutralization method
Effect:	immediate effect

Conditions:

Application time:	2 x 45 s
Volume of the product:	2 x 7 ml
Concentration:	100%

The tested product is suitable to be used as surgical hand disinfection.

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Volunteer	Chronological	Reference hand disinfection procedure RP					Reference handrub procedure with product PP					Difference
	Sequence	N prevalues	N postvalues	lg prevalues	lg postvalues	lg R	N prevalues	N postvalues	lg prevalues	lg postvalues	lg R	RP - PP
1	RP	7,30E+04	7,90E+02	4,86	2,90	1,96	6,40E+04	7,70E+02	4,81	2,89	1,92	0,04
2	RP	7,90E+04	6,60E+03	4,90	3,82	1,08	9,00E+04	1,00E+04	4,95	4,00	0,95	0,13
3	RP	7,10E+04	1,88E+03	4,85	3,27	1,58	1,06E+05	1,20E+03	5,03	3,08	1,95	-0,37
4	RP	7,90E+04	8,50E+02	4,90	2,93	1,97	5,80E+04	1,00E+02	4,76	2,00	2,76	-0,79
5	RP	9,60E+04	9,60E+03	4,98	3,98	1,00	8,90E+04	1,12E+04	4,95	4,05	0,90	0,10
6	RP	8,50E+04	2,44E+03	4,93	3,39	1,54	1,70E+04	6,70E+03	4,23	3,83	0,40	1,14
7	RP	7,70E+04	7,10E+03	4,89	3,85	1,04	1,02E+04	2,21E+03	4,01	3,34	0,67	0,37
8	RP	6,80E+04	3,80E+02	4,83	2,58	2,25	1,29E+05	9,30E+03	5,11	3,97	1,14	1,11
9	RP	5,60E+04	4,90E+03	4,75	3,69	1,06	8,30E+04	5,10E+03	4,92	3,71	1,21	-0,15
10	RP	7,10E+04	9,90E+03	4,85	4,00	0,85	7,60E+04	9,40E+03	4,88	3,97	0,91	-0,06
11	RP	1,02E+05	1,01E+04	5,01	4,00	1,01	6,90E+04	9,30E+03	4,84	3,97	0,87	0,14
12	RP	9,40E+04	1,07E+04	4,97	4,03	0,94	1,11E+05	1,24E+04	5,05	4,09	0,96	-0,02
13	PP	7,90E+04	2,91E+03	4,90	3,46	1,44	9,80E+04	7,80E+03	4,99	3,89	1,10	0,34
14	PP	9,10E+04	6,10E+03	4,96	3,79	1,17	7,80E+04	8,00E+03	4,89	3,90	0,99	0,18
15	PP	7,50E+04	3,08E+03	4,88	3,49	1,39	1,12E+04	1,56E+03	4,05	3,19	0,86	0,53
16	PP	5,20E+04	9,30E+02	4,72	2,97	1,75	1,10E+05	2,01E+02	5,04	2,30	2,74	-0,99
17	PP	8,50E+04	6,50E+03	4,93	3,81	1,12	1,02E+05	1,23E+04	5,01	4,09	0,92	0,20
18	PP	1,06E+04	2,04E+02	4,03	2,31	1,72	6,50E+03	7,50E+02	3,81	2,88	0,93	0,79
19	PP	8,00E+04	1,10E+03	4,90	3,04	1,86	1,68E+04	4,80E+02	4,23	2,68	1,55	0,31
20	PP	1,10E+05	6,00E+03	5,04	3,78	1,26	9,90E+04	8,60E+03	5,00	3,93	1,07	0,19
21	PP	6,30E+04	2,76E+02	4,80	2,44	2,36	8,70E+04	2,86E+03	4,94	3,46	1,48	0,88
22	PP	5,50E+04	4,40E+02	4,74	2,64	2,10	5,30E+04	7,10E+03	4,72	3,85	0,87	1,23
23	PP	1,18E+05	9,70E+02	5,07	2,99	2,08	8,20E+04	6,50E+03	4,91	3,81	1,10	0,98
24	PP	1,04E+05	7,60E+02	5,02	2,88	2,14	1,16E+05	1,35E+04	5,06	4,13	0,93	1,21
Ø	Overall	7,81E+04	3,94E+03	4,86	3,34	1,52	7,34E+04	6,14E+03	4,76	3,54	1,22	
s		2,23E+04	3,62E+03	0,20	0,55	0,48	3,68E+04	4,43E+03	0,38	0,61	0,59	
n				24	24	24			24	24	24	
Ø	RP → PP			4,89	3,54	1,35			4,79	3,57	1,22	0,13
s				0,07	0,51	0,48			0,33	0,64	0,66	
n				12	12	12			12	12	12	
Ø	PP → RP			4,83	3,13	1,70			4,72	3,51	1,21	0,49
s				0,28	0,53	0,42			0,44	0,61	0,53	
n				12	12	12			12	12	12	

Sorting of individual differences and computation for Hodges-Lehman 97,5% upper confidence limits													
	Sorted differences	**Mean pairwise differences (di+dii)/2**											
1	1,23	1,23											
2	1,21	1,22	1,21										
3	1,14	1,19	1,18	1,14									
4	1,11	1,17	1,16	1,13	1,11								
5	0,98	1,11	1,10	1,06	1,05	0,98							
6	0,88	1,06	1,05	1,01	1,00	0,93	0,88						
7	0,79	1,01	1,00	0,97	0,95	0,89	0,84	0,79					
8	0,53	0,88	0,87	0,84	0,82	0,76	0,71	0,66	0,53				
9	0,37	0,80	0,79	0,76	0,74	0,68	0,63	0,58	0,45	0,37			
10	0,34	0,79	0,78	0,74	0,73	0,66	0,61	0,57	0,44	0,36	0,34		
11	0,31	0,77	0,76	0,73	0,71	0,65	0,60	0,55	0,42	0,34	0,33	0,31	
12	0,20	0,72	0,71	0,67	0,66	0,59	0,54	0,50	0,37	0,29	0,27	0,26	0,20
13	0,19	0,71	0,70	0,67	0,65	0,59	0,54	0,49	0,36	0,28	0,27	0,25	0,20
14	0,18	0,71	0,70	0,66	0,65	0,58	0,53	0,49	0,36	0,28	0,26	0,25	
15	0,14	0,69	0,68	0,64	0,63	0,56	0,51	0,47	0,34	0,26	0,24		
16	0,13	0,68	0,67	0,64	0,62	0,56	0,51	0,46	0,33	0,25			
17	0,10	0,67	0,66	0,62	0,61	0,54	0,49	0,45	0,32				
18	0,04	0,64	0,63	0,59	0,58	0,51	0,46	0,42					
19	-0,02	0,61	0,60	0,56	0,55	0,48	0,43						
20	-0,06	0,59	0,58	0,54	0,53	0,46							
21	-0,15	0,54	0,53	0,50	0,48								
22	-0,37	0,43	0,42	0,39									
23	-0,79	0,22	0,21										
24	-0,99	0,12											

log R = decimal log reduction; RP→PP sequence: first RP, second PP; PP→RP sequence: first PP, second RP; Ø = mean; s = standard deviation; n = number of values (volunteer)

Difference of mean Rs (RP→PP): 1,35 - 1,22 = 0,13; Difference of mean Rs (PP→RP): 1,70 - 1,21 = 0,49 ; Absolute difference of differences: |0,13 - 0,49| = 0,36

The median is between the 12th and 13th value: [0,20 + 0,19]/2 = 0,195

The mean pairwise differences that do not exceed the median (here: 0,195) are computed. From table in EN 12791:2016+A1:2017 of critical values for Wilcoxon's matched-pairs signed-ranks test the entry for n = 24 ans a one-sided P = 0,025 level of significance, the critical value of 81 is found. **Hence c = 81 + 1 =82.** The pairwise differences are sorted in descending order. **The 82nd value is 0,59.**

Hence the Hodges-Lehmann upper one sided 97,5% confidence limit for the difference in lg Rs between RP and PP is 0**,59,** which is less than the agreed inferiority margin of 0,75.

Therefore the hypothesis of inferiority of PP is rejected and it can be concluded that the test preparation PP is non-inferior to RP.

Propan-1-ol batch No.: K52972497115, expiry date 31.12.25 60%, 2 x 3 ml, 2 x 1,5 min, immediate effect, hand disinfection procedure

Volunteer			Number of CFU per plate from dilution 10^x					
			Prevalues			Immediate postvalues		
No	Sequence	Hand (left or right)	-1	-2	-3	0	-1	-2
1	RP → PP	l	>330	>330	73	>330	79	<14
2	RP → PP	l	>330	>330	79	>330	>330	66
3	RP → PP	l	>330	>330	71	>330	186	21
4	RP → PP	l	>330	>330	79	>330	85	<14
5	RP → PP	l	>330	>330	96	>330	>330	96
6	RP → PP	l	>330	>330	85	>330	241	27
7	RP → PP	r	>330	>330	77	>330	>330	71
8	RP → PP	r	>330	>330	68	>330	38	<14
9	RP → PP	r	>330	>330	56	>330	>330	49
10	RP → PP	r	>330	>330	71	>330	>330	99
11	RP → PP	r	>330	>330	102	>330	>330	101
12	RP → PP	r	>330	>330	94	>330	>330	107
13	PP → RP	l	>330	>330	79	>330	292	28
14	PP → RP	l	>330	>330	91	>330	>330	61
15	PP → RP	l	>330	>330	75	>330	306	33
16	PP → RP	l	>330	>330	52	>330	93	<14
17	PP → RP	l	>330	>330	85	>330	>330	65
18	PP → RP	l	>330	106	<14	201	23	<14
19	PP → RP	r	>330	>330	80	>330	110	<14
20	PP → RP	r	>330	>330	110	>330	>330	60
21	PP → RP	r	>330	>330	63	269	35	<14
22	PP → RP	r	>330	>330	55	>330	44	<14
23	PP → RP	r	>330	>330	118	>330	97	<14
24	PP → RP	r	>330	>330	104	>330	76	<14

Period of analysis: 16.8.2022 - 31.8.2022

16.8.-17.8.2022, 30.8.-31.8.2022

Prepared by: Mgr. Alena Holíková

Product Dezinfectant Universal "Bio-Dez" 100%, 2 x 7 ml, 2 x 45 s, immediate effect, handrub

Volunteer			Number of CFU per plate from dilution 10^x					
			Prevalues			Immediate postvalues		
No	Sequence	Hand (left or right)	-1	-2	-3	0	-1	-2
1	RP → PP	r	>330	>330	64	>330	77	<14
2	RP → PP	r	>330	>330	90	>330	>330	101
3	RP → PP	r	>330	>330	106	>330	120	<14
4	RP → PP	r	>330	>330	58	99	<14	<14
5	RP → PP	r	>330	>330	89	>330	>330	112
6	RP → PP	r	>330	168	19	>330	>330	67
7	RP → PP	l	>330	102	<14	>330	216	27
8	RP → PP	l	>330	>330	129	>330	>330	93
9	RP → PP	l	>330	>330	83	>330	>330	51
10	RP → PP	l	>330	>330	76	>330	>330	94
11	RP → PP	l	>330	>330	69	>330	>330	93
12	RP → PP	l	>330	>330	111	>330	>330	124
13	PP → RP	r	>330	>330	98	>330	>330	78
14	PP → RP	r	>330	>330	78	>330	>330	80
15	PP → RP	r	>330	112	<14	>330	156	16
16	PP → RP	r	>330	>330	110	198	23	<14
17	PP → RP	r	>330	>330	102	>330	>330	123
18	PP → RP	r	>330	65	<14	>330	75	<14
19	PP → RP	l	>330	164	21	>330	48	<14
20	PP → RP	l	>330	>330	99	>330	>330	86
21	PP → RP	l	>330	>330	87	>330	284	31
22	PP → RP	l	>330	>330	53	>330	>330	71
23	PP → RP	l	>330	>330	82	>330	>330	65
24	PP → RP	l	>330	>330	116	>330	>330	135

Period of analysis: 16.8.2022 - 31.8.2022

16.8.-17.8.2022, 30.8.-31.8.2022

Prepared by: Mgr. Alena Holíková

REPORT OF ANALYSIS No. 80248/21/ROBCH

Client	Sample number:
ECOCHIM-GRUP SRL OR. OTACI, STR. VOITOVICI 21 2059 CHIȘINĂU	**80248/21/ROBCH** Sample description *(according to declaration of Client)* **DEZINFECTANT UNIVERSAL "BIO-DEZ"** **Lot: -** **Data fabricatie: 01.10.2021** **Data expirarii: 01.10.2024** **Data prelevarii: -** **Cantitate prelevata: 2 x 500 ml** **Responsabil prelevare: CRESTINOV ALEXANDR** **Ora receptiei probei: 15:30** **Temperatura receptie proba: 15°C** **Sample condition with no objections**
Sample received: **11.10.2021**	
Tests performed: **21.10.2021**	
Tests completed: **13.12.2021**	**Order of 11.10.2021**
Report dated: **13.12.2021**	Sampling and delivery were carried out by client.

Test	Method	Unit	Result
# * Fungicidal activity in medical area. Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area. Test method and requirements (phase 2, step 1).	EN 13624:2014	-	Test method performed by the subcontractor; the results are taken in full from the test report No D/21/ B0644 , issued by the subcontractor. The results of the analysis are listed starting with enclosure No1 to report of analysis.

Elaborated by: Mariana Ilinca, Manager of Microbiological Laboratory
Authorized by: Mariana Ilinca, Manager of Microbiological Laboratory
Approved by: Alina-Roxana Mihai, General Manager *(Approved with qualified electronic signature)*

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ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 80248/21/ROBCH

A) IDENTYFICATION OF THE SAMPLE	
Name of the product/Details about the product	**DEZINFECTANT UNIVERSAL "BIO-DEZ"** Expiration date: 01.10.2024. Manufacturer (supplier): Ecochim-Grup SRL. Storing conditions: Dry, without sun, 5-25 Celsius degree. Conditions of use: Hygienic handrub, surface disinfection, medical instruments disinfection, surgical handrub
Active compound/s and its concentration/s	Ethyl alcohol 72-76%, CAS 64-17-5 and CE 200-578-6. Benzalkonium chloride 0.024-0.029%, CAS 68424-85-1 and CE 270-325-2, Methylthionibium chloride 0.00024%, CAS 61-73-4 and 200-515-2
Concentrations requested for the assay	Pure (80%).
B) TEST METHOD	
Performed in accredited contracted partner laboratory, Scope of Accreditation Nr. 648/LE1286 Report Registration No. D/21/B0644 Quantitative evaluation assay of yeasticidal activity under dirty conditions, in the medical area (phase 2, step 1), with product Desinfectant Universal"Bio-Dez", (UNE-EN 13624: 2014 Standard).	UNE-EN 13624:2014 Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of the fungicidal or yeasticidal activity in the medical area. Test method and requirements (phase 2, step 1). AENOR.
Testing method	Procedure DESIN-1058-b // EN 13624:2014
C) INFORMATION ABOUT SAMPLE RECEPTION	
Date of reception of order with test conditions	21.10.2021
Date of reception of the sample	25.10.2021
Aspect of the received product	Blue liquid in plastic package
D) METHOD OF ASSAY AND ITS VALIDATION (UNE-EN 13624: 2014 Standard)	
Method used	Dilution-neutralization
Neutralizer	Tryptone 5 g/L, yeast extract 2.5 g/L, dextrose 10 g/L, sodium thioglycolate 1 g/L, sodium thiosulfate 1 g/L, sodium bisulphite 2.5 g/L, soy lecithin 7 g/L, polysorbate-80 5 g/L, glycine 1 g/L, l-histidine 1 g/L and Saponin 30 g/L.
E) EXPERIMENTAL CONDITIONS	
Assay period	2021/11/08 to 2021/11/14.
Solvent of the product used in the assay	Sterile distilled water.
Product concentrations for the assay	Pure (80%), 50%, 0.1%
Aspect of the dilutions of the product	Pure (80%) and 50% blue liquid; 0.1% transparent.
Contact time	60 seconds
Assay temperature	+20°C ± 1°C
Interfering substance	Bovine serum albumin 3 g/L and erythrocytes 3 mL/L.
Stability of the mixture (interfering substance and product diluted in sterile distilled water)	Stable
Temperature of incubation	+30°C± 1°C
Identification of the strain used	*Candida albicans* CECT-1394 (ATCC 10231)

ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 80248/21/ROBCH

Results of the assay

- Assay of validation ..... See tables 1 and 2.
- Evaluation of yeasticidal activity..... See table 3.
- Number of replicates per assay organism ..... 1.

Special remarks

- All controls and validation were between the basic limits.
- At least one concentration of the sample showed a log reduction lower than 4 log.
- At least one concentration of the sample showed a log reduction higher than 4 log.
- The highest concentration that can be assayed in the test (80%) is due to the mixtures to perform the assay.
- No precipitate formed during the test procedure (the test mixtures were homogeneous).

Conclusion

The product **Desinfectant Universal"Bio-Dez"**, batch not indicated, when is pure (80%), shows **yeasticidal activity** after 60 seconds at 20ºC ± 1ºC, under dirty conditions (bovine serum albumin 3 g/L and erythrocytes 3 mL/L), for the reference strain *Candida albicans* (CECT 1394 = ATCC 10231), when tested as required by the **UNE-EN 13624: 2014 Standard,**.

Note: The results obtained correspond to the sample received in the laboratory.

Quality Assurance Review:

The assay development and the results obtained have been supervised by the Director of the study.

The Quality Assurance Director has inspected the development of the assay, proving that has been realized following the proper procedure and using the adequate media, materials, and reagents, following the Good Laboratory Practices (GLPs) as well and the final report contains the primary data obtained.

Reference

- **UNE-EN 13624 : 2014**. Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of the fungicidal or yeasticidal activity in the medical area. Test method and requirements (phase 2, step 1). AENOR.

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ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 80248/21/ROBCH

Results of the assay with *Candida albicans* (CECT 1394 = ATCC 10231).

Seeding: Pour plates. No. of plates: 1 /mL.

Table 1.-Validation and controls.

Suspension of validation (Nv_0)			Control of experimental conditions (A)			Control of neutralizer (B)			Validation of the method (C) Sample concentration: Pure (80%)		
Vc_1	86	X= 90	Vc_1	72	X= 74	Vc_1	75	X= 73	Vc_1	66	X=
Vc_2	94		Vc_2	76		Vc_2	71		Vc_2	61	63.5
30 ≤ x of Nv_0 ≤ 160? Yes			x of A es ≥ 0,5 X de Nv_0? Yes			x of B es ≥ 0,5 X de Nv_0, or 0.0005 Nv_B? Yes			x of C es ≥ 0.5 X of Nv_0? Yes		
Suspension of validation (Nv_B)			Vc_1: 79 Vc_2: 77			X = 78 30 ≤ x de Nv_B/1000 ≤ 160? Yes					

Table 2. -Suspension of the assay.

	N	Vc_1	Vc_2	
Suspension of assay (N and N_0)	10^{-5}	>330	>330	$Xwm = 3.35 \times 10^7$ lg N = 7.53 $N_0 = N/10$
	10^{-6}	32	35	lg N_0 = 6.53 6.17 ≤ lg N_0 ≤ 6.70? Yes

Table 3.-Results of the activity assays with the sample.

Concentrations of the sample (%)	Dilutions steps	Vc_1	Vc_2	Lg Na = lg (X x 10 or Xmw x 10)	LgR (lg N_0 = 6.53)	Time of contact (seconds)
Pure (80%)	Na^0	<14	<14	<2.15	>4.38	60
	Na^{-1}	<14	<14			
50%	Na^0	<14	<14	<2.15	>4.38	60
	Na^{-1}	<14	<14			
0.1%	Na^0	>330	>330	>4.52	<2.01	60
	Na^{-1}	>330	>330			

Explanations:

Vc = number per mL (one or two plates); Xwm = ponderated mean of X.

X = mean of Vc_1 and Vc_2 (duplicate of 1 + 2); R (reduction): (lg R = lg N_0 – lg Na).

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Date: 08.12.2021
Authorized by: Mariana Ilinca, Manager of Microbiological laboratory
Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

HAMILTON ROMANIA

RAPORT DE INCERCARE NR. 1071/23/ROBCH/Z1

Inlocuieste Raportul de Incercare Nr. 1071/23/ROBCH din 02.03.2023

Client	Numărul eEantionului:
ECOCHIM-GRUP SRL STRADA PETRICANI 21/3 2059 CHIŞINĂU	1071/23/ROBCH Descriere obiect de incercat *(conform cu declaratia Clientului)* Dezinfectant Universal "Bio-Dez" Lot: - Data fabricatie: 13.12.2022 Data expirarii: 13.12.2025 Data prelevarii: 13.12.2021 Cantitate prelevata:500 ml Responsabil prelevare: Cristinov Alexandr Ora receptiei probei: 08:00 Temperatura receptie proba: 15°C Sample condition with no objections
Data primirii obiectului de incercat: 11.01.2023	
Data finalizarii incercarii: 02.03.2023	Comanda din 11.01.2023
Data eliberarii raportului: 02.08.2023	Probele au fost prelevate si livrate de catre Client.

Parametrii de testare	Metoda de testare	Unitate de masura	Rezultat
# * Fungicidal activity in medical area. Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area. Test method and requirements (phase 2, step 1).	EN 13624:2014	-	Test method performed by the subcontractor; the results are taken in full from the test report No D/23/ B0019 , issued by the subcontractor. The results of the analysis are listed starting with enclosure No1 to report of analysis.

Responsabil incercare: Mariana Ilinca, Sef Laborator Microbiologie
Validat de: Mariana Ilinca, Sef Laborator Microbiologie
Autorizat de: Alina-Roxana Mihai, General Manager *(Aprobat cu semnatura electronica)*

Laborator: Bucuresti 041914, sos. Berceni nr.8

* Metoda de testare acreditata # Test efectuat de catre subcontractor
ø Incercari neacreditate

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Autorizatie A.N.S.V.S.A. nr. 115 din 18.06.2018

ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 1071/23/ROBCH/Z1

A) IDENTYFICATION OF THE SAMPLE	
Name of the product/Details about the product	**Dezinfectant Universal "Bio-Dez"** Manufacturer(supplier): Ecochim-Grup Condition of use: Instrument disinfection, surface disinfection without mechanical action textile disinfection
Solvent of the product recommended by the manufacturer	Not indicated
Active(S) substance (S) and its concentration(s)	Ethyl alcool 72-76%, CAS 64-17-5 and CE 200-578-6 Benzalkonium chloride 0.024-0.029%, CAS 68424-85-1 and CE 270-325-2 Methylthionibium chloride 0.00024%, CAS 61-73-4 and 200-515-2.
Concentrations requested for the assay	80% and 97%.
B) TEST METHOD	
Performed in accredited subcontracted partner laboratory: Scope of Accreditation Nr. 648/LE1286 Report no.: D/23/B0019 and D/23/B0413- Quantitative evaluation assay of fungicidal activity in Medicine (phase 2, step1), with the product "Dezinfectant Universal "Bio-Dez"". (EN 13624 : 2022 Standard)	EN 13624: 2022. Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of the fungicidal or yeasticidal activity in the medical area. Test method and requirements (phase 2, step 1).
Testing method	EN 13624: 2022
Method	Dilution-neutralization
Neutralizer	Tryptone 5 g/L, yeast extract, 2.5 g/L, dextrose 10g/L, sodium thioglycolate 1g/L, sodium thiosulfate 1g/L, sodium bisulfide 2.5 g/L, soya lecithin 7 g/L, polysorbate-80 5 g/L, glycine 1 g/L, l-histidine 1 g/L and saponin 30 g/L.
C) INFORMATION ABOUT SAMPLE RECEPTION	
Date of reception of the sample	2023/01/13
Date of reception of order with test conditions	2023/01/16.
Date of reception of order with test conditions (test at 97%)	2023/06/14
Aspect of the received product	Blue liquid in plastic package
D) EXPERIMENTAL CONDITIONS	
Assay period	2023/02/08 to 2023/02/17 (test at 80%). 2023/07/05 to 2023/07/15 (test at 97%).
Solvent of the product used in the assay	Sterile distilled water (test at 80%). Not applicable (test at 97%).
Product concentrations for the assay	First test: 80%, 50% and 0.1% Second test: 97%.
Aspect of the dilutions of the product	97%, 80% and 50% blue liquid; 0.1% transparent liquid.
Contact time	90 seconds
Assay temperature	+20°C ± 1°C
Interfering substance	Bovine serum albumin 3 g/L plus erythrocytes 3 mL/L.
Stability of the mixture (interfering substance and product diluted in sterile distilled water)	Formation of flocs at 97% concentration and stable at 80%, 50% and 0,1%.
Temperature of incubation	+30°C ± 1°C
Identification of the origin of viral stains and number of passes	-*Aspergillus brasiliensis* (CECT 2574 = ATCC 16404). − *Candida albicans* (CECT 1394 = ATCC 10231).

ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 1071/23/ROBCH/Z1

Results of the assay

- Assay of validation ..... See tables 1, 2, 4 and 5.
- Evaluation of fungicidal activity ..... See tables 3 and 6.
- Number of replicates per assay organism ..... 1.

Special remarks

- All controls and validation were between the basic limits.
- For a valid test, at least one concentration must show a log reduction equal or higher than 4 log.
- Formation of flocs has been observed when mixed the product at 97% with the interference substance and the inoculum.
- No precipitate formed during the test procedure (test mixtures at 80%, 50 % and 0.1% were homogeneous).

Conclusion

The product **Dezinfectant Universal "Bio-Dez"**, batch 1071/23//ROBCH, at 80% **does not show fungicidal activity**, after 90 seconds at 20ºC ±1ºC, under **dirty conditions** (bovine serum albumin 3 g/L and erythrocytes 3 mL/L), because it does not show activity against *Aspergillus brasiliensis* (CECT 2574 = ATCC 16404) although it shows activity against *Candida albicans* (CECT 1394 = ATCC 10231), when tested as required by the **EN 13624: 2022 Standard**.

The product **Dezinfectant Universal "Bio-Dez"**, batch 1071/23//ROBCH, at 80% **shows yeasticidal activity**, after 90 seconds at 20ºC ±1ºC, under **dirty conditions** (bovine serum albumin 3 g/L and erythrocytes 3 mL/L), for the strain *Candida albicans* (CECT 1394 = ATCC 10231), when tested as required by the **EN 13624: 2022 Standard**.

The product **Dezinfectant Universal "Bio-Dez''**, batch 1071/23/ROBCH, at 97% concentration requested by the client, **shows fungicidal activity**, after 90 seconds at 20ºC ±1ºC, under dirty conditions (bovine serum albumin 3 g/L plus erythrocytes 3ml/L), against the reference strains *Aspergillus brasiliensis* (CECT 2574 = ATCC 16404) and *Candida albicans* (CECT 1394 = ATCC 10231), when tested as required by the **EN 13624: 2022 Standard**.

Note: The results obtained correspond to the sample received in the laboratory.

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Date: 02.08.2023
Authorized by: Mariana Ilinca, Manager of Microbiological laboratory
Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 1071/23/ROBCH/Z1

Results of the assay with *Aspergillus brasiliensis* (CECT 2574 = ATCC 16404).
First test at 80%.

Seeding: Pour plates. No. of plates: 4/mL.

Table 1.-Validation and controls.

Suspension of validation (Nv_0)			Control of experimental conditions (A)			Control of the neutralizer (B)			Validation of the method (C) Sample concentration: 80%		
Vc_1	72	X=	Vc_1	68	X=	Vc_1	61	X=	Vc_1	63	X=
Vc_2	78	75	Vc_2	66	67	Vc_2	65	63	Vc_2	69	66
$30 \leq X$ of $Nv_0 \leq$ 160? Yes			X of A is ≥0.5x X if Nv_0? Yes			X of B es ≥ 0.0005 Nv_B? Yes			X of C is ≥0.5x X of Nv_0? Yes		
Suspension of validation (Nv_B)			Vc_1: 79 Vc_2: 76			X= 77.5 $30 \leq X$ de $Nv_B/1000 \leq$ 160? Yes					

Table 2.-Suspension of the assay.

	N	Vc_1	Vc_2	
Suspension of assay (N and N_0)	10^{-5}	291	297	$Xwm = 2.94 \times 10^7$ $\lg N = 7.47$ $N_0 = N/10$
	10^{-6}	29	30	$\lg N_0 = 6.47$ $6.17 \leq \lg N_0 \leq 6.70$?; Yes

Table 3.- Results of the activity test with the sample.

Concentrations of the sample (%)	Dilutions steps	Vc_1	Vc_2	Lg Na = lg (X x 10 o Xwm x 10)	Lg R (Lg N_0=6.47)	Time of contact (seconds)
Pure (80 %)	Na^0	>660	>660	4.05	2.42	90
	Na^{-1}	115	108			
50 %	Na^0	>660	>660	>4.82	<1.65	90
	Na^{-1}	>660	>660			
0.1 %	Na^0	>660	>660	>4.82	<1.65	90
	Na^{-1}	>660	>660			

Explanations:
Vc = number per mL (one or two plates); Xwm = ponderated mean of X.
X = mean of Vc_1 and Vc_2 (duplicate of 1 + 2); R(reduction): ($\lg R = \lg N_0 - \lg Na$).

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ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 1071/23/ROBCH/Z1

Counts per plate:

(N) 10^{-5} = 70 + 73 + 74 + 74; 71 + 75 + 76 + 75;
10^{-6} = 6 + 7 + 8 + 8; 8 + 7 + 7 + 8;

Product:

Pure (80%) → Na^{-1} 28 + 27 + 31 + 30; 27 + 28 + 26 + 27;

50% → Na^{-1} = >165 + >165 + >165 + >165; >165 + >165 + >165 + >165;

0.1% → Na^{-1} = >165 + >165 + >165 + >165; >165 + >165 + >165 + >165;

A = 17+16+18+17; 17+16+16+17;
B = 15+16+15+15; 16+15+16+18;
C = 15+16+16+16; 17+18+16+18;
N_{V0} = 18+17+19+18; 19+20+20+19;
N_{VB} = 19+20+20+20; 19+19+19+19;

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ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 1071/23/ROBCH/Z1

Results of the assay with *Aspergillus brasiliensis* (CECT 2574 = ATCC 16404).
Second test at 97%.

Seeding: plate pouring; No. of plates: 4/mL.

Table 1.-Validation and controls.

Suspension of validation (Nv_0)			Control of experimental (A)			Control of the neutralizer (B)			Validation of the method (C) Sample concentration: 97%		
Vc_1	101	X =	Vc_1	80	X =	Vc_1	85	X =	Vc_1	80	X =
Vc_2	100	100.5	Vc_2	82	81	Vc_2	82	83.5	Vc_2	82	81
$30 \leq X$ of $Nv_0 \leq$ 160? Yes			X of A is ≥0.5x X if Nv_0? Yes			X of B es ≥ 0.0005 Nv_B? Yes			X of C is ≥0.5x X of Nv_0? Yes		
Suspension of validation (Nv_B)			Vc_1: 102 Vc_2: 102			X = 102 $30 \leq X$ de $Nv_B/1000 \leq$ 160? Yes					

Table 2.-Suspension of the assay.

	N	Vc_1	Vc_2	
Suspension of assay (N and N_0)	10^{-6}	199	200	$Xwm = 1.99 \times 10^8$ $\lg N = 8.30$ $N_0 = N/10$ $\lg N_0 = 7.30$
	10^{-7}	19	20	$7.17 \leq \lg N_0 \leq 7.70$?; Yes

Table 3.- Results of the activity test with the sample.

Concentrations of the sample (%)	Dilutions steps	Vc_1	Vc_2	Lg Na = lg (X x 10 o Xwm x 10)	Lg R (Lg N_0=7.30)	Time of contact (seconds)
97%	Na^0	<14	<14	<2.15	>5.15	90
	Na^{-1}	<14	<14			
	Na^{-2}	<14	<14			

Explanations:
Vc = number per mL (one or two plates); Xwm = ponderated mean of X.
X = mean of Vc_1 and Vc_2 (duplicate of 1 + 2); R(reduction): ($\lg R = \lg N_0 - \lg Na$).

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Date: 02.08.2023
Authorized by: Mariana Ilinca, Manager of Microbiological laboratory
Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 1071/23/ROBCH/Z1

Counts per plate:

(*N*) 10^{-6} = 48 + 52 + 50 + 49; 49 + 50 + 51 + 50;
10^{-7} = 4 + 5 + 5 + 5; 4 + 5 + 6 + 5.

Sample:

97% = Na^0 = 0 + 0 + 0 + 0; 0 + 0 + 0 + 0;

A = 19 + 20 + 22 + 19; 21 + 20 + 22 + 19;
B = 24 + 20 + 21 + 20; 19 + 21 + 22 + 20;
C = 20 + 21 + 20 + 19; 20 + 22 + 20 + 20;
N_{V0} = 28 + 26 + 24 + 23; 25 + 24 + 26 + 25;
N_{VB} = 27 + 24 + 26 + 25; 25 + 24 +27 + 26.

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ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 1071/23/ROBCH/Z1

Results of the assay with *Candida albicans* (CECT 1394 = ATCC 10231).
First test at 80%.

Seeding: Pour plates. No. of plates: 1 /mL.

Table 4.-Validation and controls.

Suspension of validation (Nv_0)			Control of experimental conditions (A)			Control of the neutralizer (B)			Validation of the method (C) Sample concentration: 80%		
Vc_1	96	X=	Vc_1	83	X=	Vc_1	87	X=	Vc_1	82	X=
Vc_2	100	98	Vc_2	89	86	Vc_2	100	93.5	Vc_2	85	83.5
$30 \leq X$ of $Nv_0 \leq$ 160? Yes			X of A is ≥0.5x X if Nv_0? Yes			X of B es ≥ 0.0005 Nv_B? Yes			X of C is ≥0.5x X of Nv_0? Yes		
Suspension of validation (Nv_B)			Vc_1: 85 Vc_2: 87			X = 86 $30 \leq X$ de $Nv_B/1000 \leq$ 160? Yes					

Table 5. -Suspension of the assay.

	N	Vc_1	Vc_2	
Suspension of assay (N and N_0)	10^{-5}	>330	>330	$Xwm = 3.65 \times 10^7$ $\lg N = 7.56$ $N_0 = N/10$ $\lg N_0 = 6.56$ $6.17 \leq \lg N_0 \leq 6.70$? Yes
	10^{-6}	38	35	

Table 6.-Results of the activity assays with the sample.

Concentrations of the sample (%)	Dilutions steps	Vc_1	Vc_2	Lg Na = lg (X x 10 o Xwm x 10)	Lg R (Lg N_0=6.56)	Time of contact (seconds)
Pure (80 %)	Na^0	<14	<14	<2.15	>4.41	90
	Na^{-1}	<14	<14			
50 %	Na^0	>330	>330	3.94	2.62	90
	Na^{-1}	88	87			
0.1 %	Na^0	>330	>330	>4.52	<2.04	90
	Na^{-1}	>330	>330			

Explanations:
Vc = number per mL (one or two plates); Xwm = ponderated mean of X.
X = mean of Vc_1 and Vc_2 (duplicate of 1 + 2); R (reduction): ($\lg R = \lg N_0 - \lg Na$).

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Date: 02.08.2023
Authorized by: Mariana Ilinca, Manager of Microbiological laboratory
Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 1071/23/ROBCH/Z1

Results of the assay with *Candida albicans* (CECT 1394 = ATCC 10231).
Second test at 97%.

Seeding: plate pouring; No. of plates: 1/mL.

Table 4.-Validation and controls.

Suspension of validation (Nv_0)			Control of experimental conditions (A)			Control of the neutralizer (B)			Validation of the method (C) 97%		
Vc_1	89	X = 87	Vc_1	80	X= 79.5	Vc_1	81	X= 82	Vc_1	80	X= 78
Vc_2	85		Vc_2	79		Vc_2	83		Vc_2	76	
30 ≤ X of Nv_0 ≤ 160? Yes			X of A is ≥ 0,5 x X of Nv_0? Yes			X of B is ≥ 0,5 x X of Nv_0, or 0.0005 Nv_B? Yes			X of C is ≥ 0.5 x X of Nv_0? Yes		
Suspension of validation (Nv_B)			Vc_1: 87 Vc_2: 89			X = 88 30 ≤ x de Nv_B/1000 ≤ 160? Yes					

Table 5. -Suspension of the assay.

	N	Vc_1	Vc_2	
Suspension of assay (N and N_0)	10^{-6}	>330	>330	$Xwm = 4.95 \times 10^8$ lg N = 8.69 $N_0 = N/10$
	10^{-7}	51	48	lg N_0 = 7.69 7.17 ≤ lg N_0 ≤ 7.70? Yes

Table 6.-Results of the activity assays with the sample.

Concentrations of the sample (%)	Dilutions steps	Vc_1	Vc_2	Lg Na = lg (X x 10 o Xwm x 10)	Lg R (Lg N_0=7.69)	Time of contact (seconds)
97%	Na^0	<14	<14	<2.15	>5.54	90
	Na^{-1}	<14	<14			
	Na^{-2}	<14	<14			

Explanations:
Vc = number per mL (one or two plates); Xwm = ponderated mean of X.
X = mean of Vc_1 and Vc_2 (duplicate of 1 + 2); R (reduction): (lg R = lg N_0 – lg Na).

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Date: 02.08.2023
Authorized by: Mariana Ilinca, Manager of Microbiological laboratory
Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

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ENCLOSURE No. 1 TO REPORT OF ANALYSIS NO. L21206/22/JSHR

A) IDENTIFICATION OF THE SAMPLE	
Name of the product	**Dezinfectant Universal "Bio-Dez"** Lot/Batch: - Production date: - Expiration date: 18.02.2025 Sampling date: 18.02.2022 Sampling quantity: 1x 500ml Sample temperature: 20°C Reception hour: 12:30 Responsible for sampling: Crestinov Alexandr
Active substance	Ethyl alcool 72-76%, CAS 64-17-5 and CE 200-578-6 Benzalkonium chloride 0,024-0,029%, CAS 68424-85-1 and CE 270-325-2 Methylthionibium chloride 0,00024%, CAS 61-73-4 and CE 200-515-2
B) TEST METHOD AND ITS VALIDATION	
Method	**PN-EN 13697+A1:2019-08** **Chemical disinfectants and antiseptics – Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas – Test method and requirements without mechanical action (phase 2, step 2)**
Neutralizer	Polisorbate 80- 30 g/l, saponine- 3 g/l, cysteine- 1g/l, histidine- 1g/l, sodium thiosulfate 7,5g/l
C) EXPERIMENTAL CONDITIONS	
Product test concentrations (%V/V)	0,01%, 50%, 100%
Test temperature	20°C+/-1°C
Contact time	60 seconds bacteria
Interfering substance	Dirty conditions: 3,0g/l bovine albumin
Product diluent	Sterile hard water
Temperature of incubation	36±1˚C bacteria
Identification of the bacterial and fungal strains used:	*Pseudomonas aeruginosa* ATCC 15442 *Escherichia coli ATCC 10536* *Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541

Date: 13.04.2022

Authorized by: Daria Depa, Senior Specialist Analyst, Cosmetics Microbiology Laboratory
Approved by: Hanna Wachowska, Laboratory Director (Approved with qualified electronic signature)

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ENCLOSURE No. 1 TO REPORT OF ANALYSIS NO. L21206/22/JSHR

TABELE nr 1 : RESULTS OF BACTERICIDAL/FUNGICIDAL ACTIVITY TESTS OF THE PREPARATION

INTERFERING SUBSTANCE: 3,0g/l BOVINE ALBUMIN - DIRTY CONDITIONS
CONTACT TIME: 60 seconds bacteria
TEST TEMPERATURE: 20˚C +/-1˚C
PRODUCT TEST CONCENTRATIONS: 0,01%, 50%, 100%

	BACTERIAL/FUNGAL TEST SUSPENSION : N					VALIDATION NT					VALIDATION NC				
TEST ORGANISM	DILUTION	VC1	VC2	AVERAGE	N	DILUTION	VC1	VC2	AVERAGE	NT	DILUTION	VC1	VC2	AVERAGE	NC
Pseudomonas aeruginosa ATCC 15442	1,00E-07	189	185	185	7,66	1E-04	82	81	82	6,91	1E-04	72	77	75	6,87
	1,00E-08	14	18												
Escherichia coli ATCC 10536	1,00E-06	163	166	164	6,61	1E-04	77	73	75	6,88	1E-04	66	69	68	6,83
	1,00E-07	14	17												
Staphylococcus aureus ATCC 6538	1,00E-06	158	162	159	6,60	1E-04	72	76	74	6,87	1E-04	78	77	78	6,89
	1,00E-07	15	14												
Enterococcus hirae ATCC 10541	1,00E-06	172	181	174	6,64	1E-04	81	88	85	6,93	1E-04	83	78	81	6,91
	1,00E-07	14	16												

	WATER CONTROL N_C					
TEST ORGANISM	DILUTION	VC1	VC2	AVERAGE	Nc	Nts
Pseudomonas aeruginosa ATCC 15442	1E-04	115	121	118	7,07	>100
Escherichia coli ATCC 10536	1E-04	114	105	110	7,04	>100
Staphylococcus aureus ATCC 6538	1E-04	106	102	104	7,02	>100
Enterococcus hirae ATCC 10541	1E-04	112	115	114	7,05	>100

$NC\text{-}N_C \leq \pm 0{,}3$ log

Bacteria 6,57≤ N ≤ 7,10 Nc>4 log
P.aeruginosa clean conditions 7,57≤ N ≤ 8,10

	TEST PROCEDURE FOR CONCETRATIONS % (V/V)																						
	0,01%							50%							100%								
TEST ORGANISM	DILUTION	VC1	VC2	AVERAGE	Nd	R=Nc-Nd	Nts	DILUTION	VC1	VC2	AVERAGE	Nd	R=Nc-Nd	Nts	DILUTION	VC1	VC2	AVERAGE	Nd	R=Nc-Nd	Nts
Pseudomonas aeruginosa ATCC 15442	1,00E-01	>330	>330	>330	>4,52	**<2,55**	>100	1,00E-01	0	0	0	<0,1	**>6,97**	0	1,00E-01	0	0	0	<0,1	**>6,97**	0
Escherichia coli ATCC 10536	1,00E-01	>330	>330	>330	>4,52	**<2,52**	>100	1,00E-01	0	0	0	<0,1	**>6,94**	0	1,00E-01	0	0	0	<0,1	**>6,94**	0
Staphylococcus aureus ATCC 6538	1,00E-01	>330	>330	>330	>4,52	**<2,50**	>100	1,00E-01	0	0	0	<0,1	**>6,92**	0	1,00E-01	0	0	0	<0,1	**>6,92**	0
Enterococcus hirae ATCC 10541	1,00E-01	>330	>330	>330	>4,52	**<2,53**	>100	1,00E-01	0	0	0	<0,1	**>6,95**	0	1,00E-01	0	0	0	<0,1	**>6,95**	0

CRITERIA:
Bactericidal activity- R ≥ 4 log

Vc- number of cfu/ ml (one or two plates)
N- test suspension (jtk) *0,025
NT- validation of the neutralization-dilution method
NC- neutralizer control
Nc- water control (log)
Nts- number of residual cfu recovered from test surface
Nd- number of microorganisms on the surface after applying the product (log)
R- reduction Nc-Nd (log)

Date: 13.04.2022

Authorized by: Daria Depa, Senior Specialist Analyst, Cosmetics Microbiology Laboratory
Approved by: Hanna Wachowska, Laboratory Director (Approved with qualified electronic signature)

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HAMILTON

AB 079

REPORT OF ANALYSIS No. L102366/22/JSHR

Client	Sample description *(according to declaration of Client)*
ECOCHIM-GRUP SRL OR. OTACI, STR. VOITOVICI 21 2059 CHIȘINĂU	**Dezinfectant Universal "Bio-Dez"** **Lot/Batch: -** **Production date: 21.09.2022** **Expiration date: 21.09.2025** **Sampling date: 29.09.2022** **Sampling quantity: 1x 500ml** **Sample temperature: 17°C** **Reception hour: 12:30** **Responsible for sampling: Crestinov Alexandr** **Sample condition with no objections** **Order of 2022-10-18** The samples were delivered by Client

Sample received:	**2022-10-19**
Analysis completed (the date of performance of the laboratory activity):	**2022-12-05**
Report dated:	**2022-12-05**

Test	Method	Unit	Result
* Bactericidal and/or fungicidal activity of disinfectants on non-porous surfaces - quantitative method[1)]	PN-EN 13697+A1:2019-08	-	Product undiluted (100%) shows fungicidal activity at 60 seconds, 20°C, in dirty conditions (3g/L bovine albumin) at reference strains: Candida albicans ATCC 10231 and Aspergillus brasiliensis ATCC 16404. Product diluted to 50% shows yeasticidal activity at 60 seconds, 20°C, in dirty conditions (3g/L bovine albumin) at reference strain: Candida albicans ATCC 10231.

[1)] The results of the analysis in attachment No 1 to the report of analysis.

THE END OF THE REPORT

Authorized by: Agnieszka Erber, Cosmetics Microbiology Laboratory Manager
Approved by: Hanna Wachowska, Laboratory Director *(Approved with electronic signature)*

Laboratory: Tychy 43-100, Goździków 1

* Test method accredited; # Test performed by external provider

Form PO-10/02a of 20.01.2020

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ENCLOSURE No. 1 TO REPORT OF ANALYSIS NO. L102366/22/JSHR

A) IDENTIFICATION OF THE SAMPLE	
Name of the product	**Dezinfectant Universal "Bio-Dez"**
Active substance	Ethyl alcohol 72-76%, CAS 64-17-5 and CE 200-578-6 Benzalkonium chloride 0,024-0,029%, CAS 68424-85-1 and CE 270-325-2 Methylthioninium chloride 0,00024%, CAS 61-73-4 and 200-515-2
B) TEST METHOD AND ITS VALIDATION	
Method	**PN-EN 13697+A1:2019-08** **Chemical disinfectants and antiseptics – Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas – Test method and requirements without mechanical action (phase 2, step 2)**
Neutralizer	Polisorbate 80- 30 g/l, saponine- 3 g/l, cysteine- 1g/l, histidine- 1g/l, sodium thiosulfate 7,5g/l
C) EXPERIMENTAL CONDITIONS	
Product test concentrations (%V/V)	0,01%, 50%, 100%
Test temperature	20°C+/-1°C
Contact time	1 minute fungi
Interfering substance	Dirty conditions: 3,0 g/l bovine albumin
Product diluent	Sterile hard water
Temperature of incubation	30±1°C fungi
Identification of the bacterial and fungal strains used:	*Aspergillus brasiliensis ATCC 16404* *Candida albicans ATCC10231*

Date: 01.12.2022

Authorized by: Agnieszka Erber, Manager, Cosmetics Microbiology Laboratory
Approved by: Hanna Wachowska, Laboratory Director (Approved with qualified electronic signature)

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ENCLOSURE No. 1 TO REPORT OF ANALYSIS NO. L102366/22/JSHR

TABELE nr 1 : RESULTS OF BACTERICIDAL/FUNGICIDAL ACTIVITY TESTS OF THE PREPARATION

INTERFERING SUBSTANCE: 3,0g/l BOVINE ALBUMIN - DIRTY CONDITIONS
CONTACT TIME: 60 seconds fungi
TEST TEMPERATURE: 20°C
PRODUCT TEST CONCENTRATIONS: 0,01%, 50%,100%

TEST ORGANISM	BACTERIAL/FUNGAL TEST SUSPENSION : N					VALIDATION NT					VALIDATION NC				
	DILUTION	VC1	VC2	AVERAGE	N	DILUTION	VC1	VC2	AVERAGE	NT	DILUTION	VC1	VC2	AVERAGE	NC
Aspergillus brasiliensis ATCC 16404	1,00E-05	184	191	187	5,67	1E-03	74	76	75	5,88	1E-03	66	67	67	5,82
	1,00E-06	18	19												
Candida albicans ATCC10231	1,00E-06	180	179	180	6,65	1E-03	69	65	67	5,83	1E-03	59	64	62	5,79
	1,00E-07	18	18												

TEST ORGANISM	WATER CONTROL N_C					
	DILUTION	VC1	VC2	AVERAGE	Nc	Nts
Aspergillus brasiliensis ATCC 16404	1E-03	125	127	126	6,10	>100
Candida albicans ATCC10231	1E-03	126	128	127	6,10	>100

NC-N_C ≤ ±0,3 log
NT-N_C ≤ ±0,3 log
Fungi 5,57 ≤ N ≤ 6,10 Nc>3 log
C.albicans 6,57≤ N ≤ 7,10 clean conditions

TEST ORGANISM	TEST PROCEDURE FOR CONCETRATIONS % (V/V)																					
	0.01%							50%							100%							
	DILUTION	VC1	VC2	AVERAGE	Nd	R=Nc-Nd	Nts	DILUTION	VC1	VC2	AVERAGE	Nd	R=Nc-Nd	Nts	DILUTION	VC1	VC2	AVERAGE	Nd	R=Nc-Nd	Nts
Aspergillus brasiliensis ATCC 16404	1,00E-01	>165	>165	>165	>4,22	<1,88	>165	1,00E-01	>165	>165	>165	>4,22	<1,90	>165	1,00E-01	5	6	6	2,78	3,32	1
Candida albicans ATCC10231	1,00E-01	>330	>330	>330	>4,52	<1,58	>100	1,00E-01	0	0	0,0	<0,1	>6,00	0	1,00E-01	0	0	0	<0,1	>6,00	0

CRITERIA:
Fungicidal activity– R ≥ 3 log

Vc- number of cfu/ ml (one or two plates)
N- test suspension (jtk) *0,025
NT- validation of the neutralization-dilution method
NC- neutralizer control
Nc- water control (log)
Nts- number of residual cfu recovered from test surface
Nd- number of microorganisms on the surface after applying the product (log)
R- reduction Nc-Nd (log)

Date: 01.12.2022

Authorized by: Agnieszka Erber, Manager, Cosmetics Microbiology Laboratory
Approved by: Hanna Wachowska, Laboratory Director (Approved with qualified electronic signature)

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HAMILTON ROMANIA

REPORT OF ANALYSIS No. 80249/21/ROBCH

Client	Sample number:
ECOCHIM-GRUP SRL OR. OTACI, STR. VOITOVICI 21 2059 CHIȘINĂU	**80249/21/ROBCH** Sample description *(according to declaration of Client)* **DEZINFECTANT UNIVERSAL "BIO-DEZ"** **Lot: -** **Data fabricatie: 01.10.2021** **Data expirarii: 01.10.2024** **Data prelevarii: -** **Cantitate prelevata: 1 x 500 ml** **Responsabil prelevare: CRESTINOV ALEXANDR** **Ora receptiei probei: 15:30** **Temperatura receptie proba: 15°C** **Sample condition with no objections**
Sample received: **11.10.2021**	
Tests performed: **21.10.2021**	
Tests completed: **13.12.2021**	**Order of 11.10.2021**
Report dated: **13.12.2021**	Sampling and delivery were carried out by client.

Test	Method	Unit	Result
# * Quantitative suspension test for the evaluation of bactericidal activity in medical area	EN 13727:2012+A2:2015	-	Test method performed by the subcontractor; the results are taken in full from the test report No D/21/ B0645, issued by the subcontractor. The results of the analysis are listed starting with enclosure No1 to report of analysis.

Elaborated by: Mariana Ilinca, Manager of Microbiological Laboratory
Authorized by: Mariana Ilinca, Manager of Microbiological Laboratory
Approved by: Alina-Roxana Mihai, General Manager *(Approved with qualified electronic signature)*

Laboratory: Bucuresti 041914, sos. Berceni nr.8

* Test method accredited # Test performed by external provider
ø Non accredited methods

PGL 09 F 01 Ed. 1 Rev. 1

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ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 80249/21/ROBCH

A) IDENTYFICATION OF THE SAMPLE	
Name of the product/Details about the product	**DEZINFECTANT UNIVERSAL "BIO-DEZ"** Expiration date: 01.10.2024. Manufacturer (supplier): Ecochim-Grup SRL. Storing conditions: Dry, without sun, 5-25 Celsius degree. Conditions of use: Hygienic handrub, surface disinfection, medical instruments disinfection, surgical handrub
Active compound/s and its concentration/s	Ethyl alcohol 72-76%, CAS 64-17-5 and CE 200-578-6. Benzalkonium chloride 0.024- 0.029%, CAS 68424-85-1 and CE 270-325-2, Methylthionibium chloride 0.00024%, CAS 61-73-4 and 200-515-2
Concentrations requested for the assay	Pure (80%).
B) TEST METHOD	
Performed in accredited contracted partner laboratory, Scope of Accreditation Nr. 648/LE1286 Report Registration No. D/21/B0645 Quantitative evaluation assay of the bactericidal activity under dirty conditions, in the medical area (phase 2, step 1) with product Desinfectant Universal"Bio-Dez", (UNE-EN 13727: 2012 + A2: 2015 Standard).	UNE-EN 13727: 2012 + A2: 2015. Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants for instruments used in Medicine. Test method and requirements (phase 2, step 1). AENOR.
Testing method	DESIN-1031-b //EN 13727: 2012 + A2: 2015
C) INFORMATION ABOUT SAMPLE RECEPTION	
Date of reception of order with test conditions	21.10.2021
Date of reception of the sample	25.10.2021
Aspect of the received product	Blue liquid in plastic package
D) METHOD OF ASSAY AND ITS VALIDATION (UNE-EN 13727: 2012+A2: 2015 Standard.)	
Method used	Dilution-neutralization
Neutralizer	Tryptone 5 g/L, yeast extract 2.5 g/L, dextrose 10 g/L, sodium thioglycolate 1 g/L, sodium thiosulfate 1 g/L, sodium bisulphite 2.5 g/L, soya lecithin 7 g/L, polysorbate-80 5 g/L, glycine 1 g/L, l-histidine 1 g/L and saponin 30 g/L.
E) EXPERIMENTAL CONDITIONS	
Assay period	2021/11/10 to 2021/11/14.
Solvent of the product used in the assay	Sterile distilled water.
Product concentrations for the assay	Pure (80%), 50%, 0.1%
Aspect of the dilutions of the product	Pure (80%) and 50% blue liquid; 0.1% transparent.
Contact time	60 seconds
Assay temperature	+20°C ± 1°C
Interfering substance	Bovine serum albumin 3 g/L and erythrocytes 3 mL/L.
Stability of the mixture (interfering substance and product diluted in sterile distilled water)	Stable
Temperature of incubation	+36°C± 1°C
Identification of the strain used	− *Pseudomonas aeruginosa* (CECT 116 = ATCC 15442). − *Staphylococcus aureus* (CECT 239 = ATCC 6538). − *Enterococcus hirae* (CECT 4081 = ATCC 10541). − *Escherichia coli K12* (CECT 433 = NCTC 10538).

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ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 80249/21/ROBCH

Results of the assay

- Assay of validation ..... See tables 1, 2, 4, 5, 7, 8, 10 and 11.
- Evaluation of bactericidal activity..... See tables 3, 6, 9 and 12.
- Number of replicates per assay organism .. 1.

Special remarks

- All controls and validation were between the basic limits.
- At least one concentration of the sample showed a log reduction lower than 5 log.
- At least one concentration of the sample showed a log reduction higher than 5 log.
- The highest concentration that can be assayed in the test (80%) is due to the mixtures to perform the assay.
- No precipitate formed during the test procedure (the test mixtures were homogeneous).

Conclusion

The product **Desinfectant Universal"Bio-Dez"**, batch not indicated, when is pure (80%), **shows bactericidal activity** after 60 seconds at 20ºC ± 1ºC, under dirty conditions (bovine serum albumin 3 g/L and erythrocytes 3 mL/L), for the reference strains *Pseudomonas aeruginosa* (CECT 116 = ATCC 15442), *Staphylococcus aureus* (CECT 239 = ATCC 6538), *Enterococcus hirae* (CECT 4081 = ATCC 10541) and *Escherichia coli* K12 (CECT 433 = NCTC 10538), when tested according to **UNE-EN 13727: 2012 + A2: 2015 Standard**.

Note: The results obtained correspond to the sample received in the laboratory.

Quality Assurance Review:

The assay development and the results obtained have been supervised by the Director of the study.

The Quality Assurance Director has inspected the development of the assay, proving that has been realized following the proper procedure and using the adequate media, materials, and reagents, following the Good Laboratory Practices (GLPs) as well and the final report contains the primary data obtained.

Reference

- **UNE-EN 13727: 2012 + A2: 2015.** Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants for instruments used in Medicine. Test method and requirements (phase 2, step 1). AENOR.

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ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 80249/21/ROBCH

Results of the assay (Bactericidal suspension) with *Pseudomonas aeruginosa* (CECT 116 = ATCC 15442).

Seeding: Pour plate; No. of plates: 1/mL.

Table 1.-Validation and controls

Suspension of validation (Nv_0)			Control of experimental conditions (A)			Control of neutralizer (B)			Validation of the method (C) Sample concentration: Pure (80%)		
Vc_1	61	X=	Vc_1	53	X= 54	Vc_1	46	X= 48	Vc_1	42	X=
Vc_2	56	58.5	Vc_2	55		Vc_2	50		Vc_2	37	39.5
30 ≤ x of Nv_0 ≤ 160? Yes			x of A es ≥ 0,5 X de Nv_0? Yes			x of B es ≥ 0,5 X de Nv_0, or 0.0005 Nv_B? Yes			x of C es ≥ 0.5 X of Nv_0? Yes		
Suspension of validation (Nv_B)			Vc_1: 57 Vc_2: 63			X = 60 30 ≤ x de Nv_B/1000 ≤ 160? Yes					

Table 2.-Suspension of the assay

	N	Vc_1	Vc_2	
Suspension of assay (N and N_0)	10^{-6}	217	234	Xwm = 2.25 x 10^8, lg N = 8.35 N_0 = N/10; lg N_0 = 7.35
	10^{-7}	21	22	7.17 ≤ lg N_0 ≤ 7.70? Yes

Table 3.-Results of the activity assays with the sample

Concentrations of the sample (%)	Dilutions steps	Vc_1	Vc_2	Lg Na = lg (X x 10 o Xwm x 10)	Lg R (Lg N_0=7.35)	Time of contact (seconds)
Pure (80%)	Na^0	<14	<14	<2.15	>5.20	60
	Na^{-1}	<14	<14			
50%	Na^0	<14	<14	<2.15	>5.20	60
	Na^{-1}	<14	<14			
0.1%	Na^0	>330	>330	>4.52	<2.83	60
	Na^{-1}	>330	>330			

Explanations:

Vc = number per mL (one or two plates); Xwm = weighted mean of X.

X = mean of Vc_1 and Vc_2 (duplicate of 1 + 2);

Logarithmic reduction R: ($\lg R = \lg N_0 - \lg Na$).

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ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 80249/21/ROBCH

Results of the assay (Bactericidal suspension) with *Staphylococcus aureus* (CECT 239 = ATCC 6538).

Seeding: Pour plate; No. of plates: 1/mL.

Table 4.-Validation and controls

Suspension of validation (Nv_0)			Control of experimental conditions (A)			Control of neutralizer (B)			Validation of the method (C) Sample concentration: Pure (80%)		
Vc_1	77	X= 74	Vc_1	68	X=	Vc_1	75	X=	Vc_1	70	X= 66
Vc_2	71		Vc_2	69	68.5	Vc_2	82	78.5	Vc_2	62	
30 ≤ x of Nv_0 ≤ 160? Yes			x of A es ≥ 0,5 X de Nv_0? Yes			x of B es ≥ 0,5 X de Nv_0, or 0.0005 Nv_B? Yes			x of C es ≥ 0.5 X of Nv_0? Yes		
Suspension of validation (Nv_B)			Vc_1: 79 Vc_2: 86			X = 82.5 30 ≤ x de Nv_B/1000 ≤ 160? Yes					

Table 5.-Suspension of the assay

	N	Vc_1	Vc_2	
Suspension of assay (N and N_0)	10^{-6}	>330	>330	Xwm = 3.40 x 10^8, lg N = 8.53 N_0 = N/10; lg N_0 = 7.53 7.17 ≤ lg N_0 ≤ 7.70? Yes
	10^{-7}	33	35	

Table 6.-Results of the activity assays with the sample

Concentrations of the sample (%)	Dilutions steps	Vc_1	Vc_2	Lg Na = lg (X x 10 o Xwm x 10)	Lg R (Lg N_0=7.53)	Time of contact (seconds)
Pure (80%)	Na^0	<14	<14	<2.15	>5.38	60
	Na^{-1}	<14	<14			
50%	Na^0	<14	<14	<2.15	>5.38	60
	Na^{-1}	<14	<14			
0.1%	Na^0	>330	>330	>4.52	<3.01	60
	Na^{-1}	>330	>330			

Explanations:
Vc = number per mL (one or two plates); Xwm = weighted mean of X.
X = mean of Vc_1 and Vc_2 (duplicate of 1 + 2);
Logarithmic reduction R: (lg$R$ = lg N_0 – lg Na).

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ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 80249/21/ROBCH

Results of the assay (Bactericidal suspension) with *Enterococcus hirae* (CECT 4081 = ATCC 10541).

Seeding: Pour plate; No. of plates: 1/mL.

Table 7.-Validation and controls

Suspension of validation (Nv_0)			Control of experimental conditions (A)			Control of neutralizer (B)			Validation of the method (C) Sample concentration: Pure (80%)		
Vc_1	41	X= 43	Vc_1	44	X=	Vc_1	37	X=	Vc_1	35	X= 36
Vc_2	45		Vc_2	43	41.5	Vc_2	40	38.5	Vc_2	37	
30 ≤ x of Nv_0 ≤ 160? Yes			x of A es ≥ 0,5 X de Nv_0? Yes			x of B es ≥ 0,5 X de Nv_0, or 0.0005 Nv_B? Yes			x of C es ≥ 0.5 X of Nv_0? Yes		
Suspension of validation (Nv_B)			Vc_1: 39 Vc_2: 42			X = 40.5 30 ≤ x de Nv_B/1000 ≤ 160? Yes					

Table 8.-Suspension of the assay

	N	Vc_1	Vc_2	
Suspension of assay (N and N_0)	10^{-6}	167	154	Xwm = 1.61 x 10^8, lg N = 8.20 N_0 = N/10; lg N_0 = 7.20 7.17 ≤ lg N_0 ≤ 7.70? Yes
	10^{-7}	17	16	

Table 9.-Results of the activity assays with the sample

Concentrations of the sample (%)	Dilutions steps	Vc_1	Vc_2	Lg Na = lg (X x 10 o Xwm x 10)	Lg R (Lg N_0=7.20)	Time of contact (seconds)
Pure (80%)	Na^0	<14	<14	<2.15	>5.05	60
	Na^{-1}	<14	<14			
50%	Na^0	15	14	2.16	5.04	60
	Na^{-1}	<14	<14			
0.1%	Na^0	>330	>330	>4.52	<2.68	60
	Na^{-1}	>330	>330			

Explanations:
Vc = number per mL (one or two plates); Xwm = weighted mean of X.
X = mean of Vc_1 and Vc_2 (duplicate of 1 + 2);
Logarithmic reduction R: ($\lg R = \lg N_0 - \lg Na$).

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ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 80249/21/ROBCH

Results of the assay (Bactericidal suspension) with *Escherichia coli K12* (CECT 433 = NCTC 10538).

Seeding: Pour plate; No. of plates: 1/mL.

Table 10.-Validation and controls

Suspension of validation (Nv_0)			Control of experimental conditions (A)			Control of neutralizer (B)			Validation of the method (C) Sample concentration: Pure (80%)		
Vc_1	58	X= 60	Vc_1	44	X= 45	Vc_1	51	X= 50	Vc_1	43	X= 41
Vc_2	62		Vc_2	46		Vc_2	49		Vc_2	39	
30 ≤ x of Nv_0 ≤ 160? Yes			x of A es ≥ 0,5 X de Nv_0? Yes			x of B es ≥ 0,5 X de Nv_0, or 0.0005 Nv_B? Yes			x of C es ≥ 0.5 X of Nv_0? Yes		
Suspension of validation (Nv_B)			Vc_1: 54 Vc_2: 56			X = 55 30 ≤ x de Nv_B/1000 ≤ 160? Yes					

Table 11.-Suspension of the assay

	N	Vc_1	Vc_2	
Suspension of assay (N and N_0)	10^{-6}	241	259	Xwm = 2.49 x 10^8, lg N = 8.40 N_0 = N/10; lg N_0 = 7.40 7.17 ≤ lg N_0 ≤ 7.70? Yes
	10^{-7}	22	25	

Table 12.-Results of the activity assays with the sample

Concentrations of the sample (%)	Dilutions steps	Vc_1	Vc_2	Lg Na = lg (X x 10 o Xwm x 10)	Lg R (Lg N_0=7.40)	Time of contact (seconds)
Pure (80%)	Na^0	<14	<14	<2.15	>5.25	60
	Na^{-1}	<14	<14			
50%	Na^0	<14	<14	<2.15	>5.25	60
	Na^{-1}	<14	<14			
0.1%	Na^0	>330	>330	>4.52	<2.88	60
	Na^{-1}	>330	>330			

Explanations:
Vc = number per mL (one or two plates); Xwm = weighted mean of X.
X = mean of Vc_1 and Vc_2 (duplicate of 1 + 2);
Logarithmic reduction R: (lg$R$ = lg N_0 – lg Na).

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REPORT OF ANALYSIS No. 17898/21/ROBCH

Client **ECOCHIM-GRUP SRL** OR. OTACI, STR. VOITOVICI 21 2059 CHIȘINĂU	Sample number: **17898/21/ROBCH** Sample description *(according to declaration of Client)* **DEZINFECTANT UNIVERSAL "BIO-DEZ"** **Sample quantity: 1 pcs x 1 L** **Production date: 26.01.2021** **Expiration date: 26.01.2024** **Sampling date: 22.02.2021** **Sample temperature: 15°C** **Reception hour: 15:00** **Responsible for sampling: Crestinov Alexandr**
Sample received: **15.03.2021** Tests performed: **21.04.2021** Tests completed: **16.06.2021** Report dated: **16.06.2021**	**Sample condition with no objections** **Order of 15.03.2021** Sampling and delivery were carried out by client.

Test	Method	Unit	Result
# * Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants. Test methods and requirements (phase 2, step 1)	EN 14348: 2005	-	Test method performed by the subcontractor; the results are taken in full from the test report No D/21/ B0152, issued by the subcontractor. The results of the analysis are listed starting with enclosure No1 to report of analysis.

Elaborated by: Mariana Ilinca, Manager of Microbiological Laboratory
Authorized by: Mariana Ilinca, Manager of Microbiological Laboratory
Approved by: Alina-Roxana Mihai, General Manager *(Approved with qualified electronic signature)*

* Test method accredited # Test performed by external provider
ø Non accredited methods

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ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 17898/21/ROBCH

A) IDENTYFICATION OF THE SAMPLE	
Name of the product/Details about the product	**DEZINFECTANT UNIVERSAL "BIO-DEZ"** Expiration date: 26.01.2024 Manufacturer (supplier): ECOCHIM-GRUP Storing conditions: Dry, without sun, 5-25 Celsius degree. Conditions of use: Handrub
Active(S) substance (S) and its concentration(s)	Ethyl alcohol 72-76%, CAS 64-17-5 and CE 200-578-6; Benzalkonium chloride 0.024-0.029%, CAS 68424-85-1 and CE 270-325-2; Methylthioninium chloride 0.00024%, CAS 61-73-4 and 200
Concentrations requested for the assay	3%/ on May 5 the client requested to perform the test at 80% concentration (Pure).
B) TEST METHOD	
Performed in accredited subcontracted partner laboratory: Scope of Accreditation Nr. 648/LE1286 Report D/21/B0152 Mycobactericidal and tuberculocidal activity of chemical disinfectants in the medical area including instrument disinfectants under clean conditions with the product **DEZINFECTANT UNIVERSAL "BIO-DEZ"** with deviations from the standard **(UNE-EN 14348: 2005 Standard)**	UNE-EN 14348: 2005. Chemical disinfectants and antiseptics . Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants. Test methods and requirements (phase 2, step 1). AFNOR
C) METHOD OF ASSAY AND ITS VALIDATION (UNE-EN 14348: 2005 Standard)	
Testing method	DESIN-1052-b // EN 14348: 2005
Method used	Dilution-neutralization
Neutralizer	Tryptone 5 g/L, yeast extract 2.5 g/L, dextrose 10 g/L, sodium thioglycolate 1 g/L, sodium thiosulfate 1 g/L, sodium bisulphite 2.5 g/L, soya lecithin 7 g/L, polysorbate-80 5 g/L, glycine 1 g/L, l-histidine 1 g/L and saponim 30 g/L.
D) INFORMATION ABOUT SAMPLE RECEPTION	
Date of reception of the sample	24.03.2021
Date of reception of order with test conditions	14.04.2021: 3% concentration 05.05.2021: 80% concentration
Aspect of the received product	Blue liquid in plastic package.
E) EXPERIMENTAL CONDITIONS	
Assay period	2021/04/12 to 2021/05/24 (including prior preparation of the strains)
Solvent of the product used in the assay	Sterile hard water
Product concentrations for the assay	Pure (80%), 3% and 0.1%
Aspect of the dilutions of the product	Pure (80%) Blue liquid; 3% and 0.1% transparent
Contact time	60 seconds
Assay temperature	20°C ± 1°C
Interfering substance	Bovine albumin 0.3 g/L
Stability of the mixture (interfering substance and product diluted in sterile hard water)	stable
Temperature of incubation	36°C ± 1°C
Identification of the origin of viral stains and number of passes	*Mycobacterium avium* (ATCC 15769) *Mycobacterium terrae* (CECT 3028 = ATCC 15755)

ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 17898/21/ROBCH

Results of the assay

- Control and validation assays..... See tables 1, 2, 4 and 5
- Evaluation of mycobactericidal activity... See tables 3 and 6.
- Number of replicates for each assay microorganism..... 1.

Special remarks

- All controls and validation were between the basic limits.
- One concentration of the sample at least showed a log reduction less than 4 log.
- One concentration of the sample at least showed a log reduction higher than 4 log.
- The highest concentration that can be assayed in the test (80%) is due to the mixtures to perform the assay.
- When the client requested to perform the test at 80% concentration, the test had been started, using hard water.

Conclusion

The product **DEZINFECTANT UNIVERSAL „BIO-DEZ"**, batch not indicated, when tested pure (80%), **shows mycobactericidal activity** after 60 seconds at 20ºC under clean conditions (bovine albumin 0.3 g/L), against *Mycobacterium avium* (ATCC 15769) and *Mycobacterium terrae* (CECT 3028 = ATCC 15755), when tested as required by **UNE-EN 14348: 2005 Standard** with deviations from the standard since the dilutions of the product, ready to use, have been prepared in sterile hard water instead of in sterile distilled water. The client informed us that the product was ready to use once the test have been started.

Note: The results obtained correspond to the sample received in the laboratory.

Quality Assurance Review:

The assay development and the results obtained have been supervised by the Director of the study.

The Quality Assurance Director has inspected the development of the assay, proving that has been realized following the proper procedure and using the adequate media, materials and reagents, following as well the Good Laboratory Practices (GLPs) and the final report contains the primary data obtained.

Reference:

- **UNE-EN 14348: 2005**. Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants. Test methods and requirements (phase 2, step 1). AENOR.

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ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 17898/21/ROBCH

Table 1.-Assay with *Mycobacterium avium* (ATCC 15769): Validation and controls.

Suspension of validation (Nv_0)			Control of experimental conditions (A)			Neutralizer (B)			Validation of the method (C) with sample concentration: Pure (80%)		
Vc_1	135	X=	Vc_1	125	X= 122	Vc_1	121	X= 124	Vc_1	130	X=
Vc_2	124	129.5	Vc_2	119		Vc_2	127		Vc_2	119	124.5
30 ≤ x of Nv_0 ≤ 160? Yes			x of A is ≥ 0.5 x X of Nv_0? Yes			x of B is ≥ 0.5 x of Nv_0? Yes			x of C is ≥ 0.5 X of Nv_0? Yes		

Table 2.- Assay with *Mycobacterium avium* (ATCC 15769): Suspension of the assay.

Suspension of the assay (N y N_0)	N	Vc_1	Vc_2	$X_{wm} = 4.85 \times 10^9 = \lg = 9.69$ $N_0 = N/10 = \lg = 8.69$ $8.17 \leq N_0 \leq 8.70$? Yes
	10^{-7}	>660	>660	
	10^{-8}	51	46	

Table 3.- Assay with *Mycobacterium avium* (ATCC 15769).

Concentrations of the sample (%)	Dilutions	Vc_1	Vc_2	Lg Na = lg (X x 10 o Xwm x 10)	LgR (lgN_0= 8.69)	Time of contact (seconds)
Pure (80%)	10^0	<14	<14	<2.15	>6.54	60
	10^{-1}	<14	<14			
	10^{-2}	<14	<14			
	10^{-3}	<14	<14			
3%	10^0	>660	>660	>6.82	<1.87	60
	10^{-1}	>660	>660			
	10^{-2}	>660	>660			
	10^{-3}	>660	>660			
0.1%	10^0	>660	>660	>6.82	<1.87	60
	10^{-1}	>660	>660			
	10^{-2}	>660	>660			
	10^{-3}	>660	>660			

Observations:

N 10^{-7}: >330 + >330; >330 + >330;
10^{-8}: 28 + 23; 27 + 19;

Nv₀: 74 + 61; 59 + 65;
A: 68 + 57; 60 + 59;
B: 63 + 58; 71 + 57;
C: 72 + 58; 55 + 64;

Na Pure (80%) 10^0: 0 + 0; 0 + 0;
3% 10^{-3}: >330 + >330; >330 + >330;
0.1% 10^{-3}: >330 + >330; >330 + >330;

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ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 17898/21/ROBCH

Table 4.-Assay with *Mycobacterium terrae* (CECT 3028 = ATCC 15755): Validation and controls.

Suspension of validation (Nv_0)			Control of experimental conditions (A)			Neutralizer (B)			Validation of the method (C) with sample concentration: Pure (80%)		
Vc_1	53	X= 55	Vc_1	54	X= 52	Vc_1	50	X= 49	Vc_1	49	X= 47
Vc_2	57		Vc_2	50		Vc_2	48		Vc_2	45	
30 ≤ x of Nv_0 ≤ 160? Yes			x of A is ≥ 0.5 x X of Nv_0? Yes			x of B is ≥ 0.5 x of Nv_0? Yes			x of C is ≥ 0.5 X of Nv_0? Yes		

Table 5.- Assay with *Mycobacterium terrae* (CECT 3028 = ATCC-15755): Suspension of the assay.

Suspension of the assay (N y N_0)	N	Vc_1	Vc_2	$X_{wm} = 2.19 \times 10^9 = \lg = 9.34$ $N_0 = N/10 = \lg = 8.34$ $8.17 \leq N_0 \leq 8.70$? Yes
	10^{-7}	227	211	
	10^{-8}	21	22	

Table 6.- Assay with *Mycobacterium terrae* (CECT 3028 = ATCC 15755).

Concentrations of the sample (%)	Dilutions	Vc_1	Vc_2	Lg Na = lg (X x 10 o Xwm x 10)	LgR (lgN_0= 8.34)	Time of contact (seconds)
Pure (80%)	10^0	<14	<14	<2.15	>6.19	60
	10^{-1}	<14	<14			
	10^{-2}	<14	<14			
	10^{-3}	<14	<14			
3%	10^0	>660	>660	>6.82	<1.52	60
	10^{-1}	>660	>660			
	10^{-2}	>660	>660			
	10^{-3}	>660	>660			
0.1%	10^0	>660	>660	>6.82	<1.52	60
	10^{-1}	>660	>660			
	10^{-2}	>660	>660			
	10^{-3}	>660	>660			

Observations:

N 10^{-7}: 103 + 124; 99 + 112;
10^{-8}: 13 + 8; 10 + 12;

Na Pure (80%) 10^0: 0 + 0; 0 + 0;
3% 10^{-3}: >330 + >330; >330 + >330;
0.1% 10^{-3}: >330 + >330; >330 + >330;

Nv₀: 29 + 24; 32 + 25;
A: 31 + 23; 26 + 24;
B: 19 + 31; 27 + 21;
C: 33 + 16; 21 + 24;

Explanations:
Vc: Counts per mL
Xwm: ponderated mean of X
X: Values of Vc_1 and Vc_2 (1. + 2. duplicates); *R*: reduction (LgR = lgN_0 – lgNa)
R: reduction (LgR = lgN_0 – lgNa)

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Date: 09.06.2021
Authorized by: Mariana Ilinca, Manager of Microbiological laboratory
Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 17898/21/ROBCH

*Test method accredited # Test performed by subcontractor. Ø Non accredited methods.

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Date: 09.06.2021
Authorized by: Mariana Ilinca, Manager of Microbiological laboratory
Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

REPORT OF ANALYSIS No. 60362/23/ROBCH

Client **ECOCHIM-GRUP SRL** OR. UNGHENI, STR. NAȚIONALĂ 119 - REPUBLICA MOLDOVA	Sample number: **60362/23/ROBCH** Sample description *(according to declaration of Client)* **Dezinfectant Universal "Bio-Dez"** **Lot: -** **Data fabricatiei: 05.08.2023** **Data expirare: 05.08.2026** **Data receptiei probei: 23.08.2023** **Cantitate prelevata:500 ml** **Responsabil prelevare: Cristinov Alexandr** **Ora receptiei probei: 12:30** **Temperatura receptie proba: 17°C** **Sample condition with no objections**
Sample received: **24.08.2023** Tests performed: **30.08.2023** Tests completed: **30.10.2023** Report dated: **30.10.2023**	**Order of 24.08.2023** Sampling and delivery were carried out by client.

Test	Method	Unit	Result
# * Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of virucidal activity in the medical area	UNE-EN 14476:2014 + A2:2019	-	Test method performed by the subcontractor; the results are taken in full from the test report No D/23/ V0259, issued by the subcontractor. The results of the analysis are listed starting with enclosure No1 to report of analysis.

Test responsible: Mariana Ilinca, Manager of Microbiological Laboratory
Validated by: Mariana Ilinca, Manager of Microbiological Laboratory
Authorized by: Alina-Roxana Mihai, General Manager *(Approved with qualified electronic signature)*

Laboratory: Bucuresti 041914, sos. Berceni nr.8

* Test method accredited # Test performed by external provider
ø Non accredited methods

PGL 09 F 01 Ed. 1 Rev. 3

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ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 60362/23/ROBCH

A) IDENTYFICATION OF THE SAMPLE	
Name of the product/Details about the product	**DEZINFECTANT UNIVERSAL "BIO-DEZ"** Manufacturer(supplier): Ecochim-Grup Condition of use: Instrument disinfection, surface disinfection, hygienic handrub.
Active(s) Substance(s) and its concentration(s)	Ethyl alcool 72-76%, CAS 64-17-5 and CE 200-578-6, Benzalkonium chloride 0.024-0.029%, CAS 68424-85-1 and CE 270-325-2, Methylthionibium chloride 0.00024%, CAS 61-73-4 and 200-515-2.
Concentration ordered for the assay	80
B) TEST METHOD	
Performed in accredited subcontracted partner laboratory: Scope of Accreditation Nr. 648/LE1286 Report D/23/V0259. Quantitative suspension test for the evaluation of virucidal activity in the medical area (phase 2, step 1), against Poliovirus type 1, Adenovirus type 5 and Murine Norovirus with the product "Dezinfectant Universal "Bio-Dez" (EN 14476: 2013 + A2: 2019 Standard)	EN 14476: 2013 + A2: 2019 Standard. Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of virucidal activity in the medical area. Test method and requirements (phase 2/step1).
Testing method	Procedure DESIN-1078 (EN 14476: 2013 + A2: 2019 Standard).
C) INFORMATION ABOUT SAMPLE RECEPTION	
Date of reception of the sample	2023/08/30
Date of reception of order with test conditions	2023/09/04.
Aspect of the received product	Blue transparent liquid in plastic container with identification label.
D) EXPERIMENTAL CONDITIONS	
Assay period	2023/09/06 to 2023/09/21.
Assay temperature	37°C ± 1°C
Titration method	TCID50 (Tissue Culture Infective Dose 50%).
Product concentrations for the assay	80%, 50% and 0.1%
Contact time	60 seconds
Contact temperature	20°C ± 1°C
Procedure to stop product cytotoxicity	Molecular sieving (< 4 columns).
Procedure to stop product activity	Cooling with ice
Solvent of the product used in the assay	Sterile distilled water
Aspect of the dilutions of the product	Transparent
Stability of the mixture (interfering substance and product diluted in sterile hard water/distilled water)	Stable
Interfering substance	Dirty conditions in the presence of bovine serum albumin 3 g/L and erythrocytes 3 mL/L.
Identification of the origin of viral stains and number of passes	Poliovirus type 1 (ATCC VR-192) aliquot: 2023/03/23 passage 2. Adenovirus type 5 (ATCC VR-5) aliquot: 2022/06/10 passage 2. Murine Norovirus (strain S99 Berlin) aliquot: 2022/06/22 passage 2.
Cell lines (name, origin, number of passes)	Vero, ref: FTVE, working aliquot 4, passages 18 21, 22 and 25. Raw 264.7, Public Health England, working aliquot 4, passages 18, 21 and 25

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Authorized by: Mariana Ilinca, Manager of Microbiological laboratory
Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 60362/23/ROBCH

Validation of assay results

Poliovirus type 1 (ATCC VR-192)

Titre of the viral suspension for the virus control (at the requested test time)
- Dirty conditions ..... log $10^{-7.50}$

Cytotoxicity level (80%) ..... log $10^{-0.50}$

Maximum level of virus inactivation detectable (difference between the titre of the viral suspension and the cytotoxicity level):
- Dirty conditions ..... log $10^{-7.00}$

Adenovirus type 5 (ATCC VR-5)

Titre of the viral suspension for the virus control (at the requested test time)
- Dirty conditions ..... log $10^{-6.82}$

Cytotoxicity level (80%) ..... log $10^{-0.50}$

Maximum level of virus inactivation detectable (difference between the titre of the viral suspension and the cytotoxicity level):
- Dirty conditions ..... log $10^{-6.32}$

Murine Norovirus (strain S99 Berlin)

Titre of the viral suspension for the virus control (at the requested test time)
- Dirty conditions ..... log $10^{-8.32}$

Cytotoxicity level (80%) ..... log $10^{-0.50}$

Maximum level of virus inactivation detectable (difference between the titre of the viral suspension and the cytotoxicity level):
- Dirty conditions ..... log $10^{-7.82}$

Reference test (formaldehyde 1.4%)

Cytotoxicity level of formaldehyde 0.7% ..... log $10^{-0.50}$

Viral quantification in the reference test (formaldehyde) after 60 minutes and with Poliovirus type 1 ..... log $10^{-3.08}$

Viral quantification in the reference test (formaldehyde) after 60 minutes and with Adenovirus type 5 ..... log $10^{-2.75}$

Viral quantification in the reference test (formaldehyde) after 60 minutes and with Murine Norovirus ..... log $10^{-4.99}$

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Confidence interval

Titre of virus with 95% confidence interval with Poliovirus type 1 (at the requested test time)

- Dirty conditions ..... $\log 10^{-7.50 \pm 0.37}$

Titre of virus with 95% confidence interval with Adenovirus type 5 (at the requested test time)

- Dirty conditions ..... $\log 10^{-6.82 \pm 0.41}$

Titre of virus with 95% confidence interval with Murine Norovirus (at the requested test time)

- Dirty conditions ..... $\log 10^{-8.32 \pm 0.42}$

Reduction with the confidence interval of 95% ..... See tables 1, 3 and 5.

Sensitivity of cells to virus

- Viral quantification of Poliovirus type 1 with cells not treated by the test solution with the test sample ..... $\log 10^{-8.23}$
- Viral quantification of Poliovirus type 1 with cells treated by the test solution with the test sample ..... $\log 10^{-7.65}$

- Viral quantification of Adenovirus type 5 with cells not treated by the test solution with the test sample ..... $\log 10^{-7.41}$
- Viral quantification of Adenovirus type 5 with cells treated by the test solution with the test sample ..... $\log 10^{-6.74}$

- Viral quantification of Murine Norovirus with cells not treated by the test solution with the test sample ..... $\log 10^{-8.66}$

  Viral quantification of Murine Norovirus with cells treated by the test solution with the test sample ..... $\log 10^{-7.99}$

  Note: only can be used to determine the infectivity of cells, those dilutions which: a) show a low degree of cellular destruction (< 25% of cell monolayer) and b) produce a reduction of the title of the virus < 1 $\log_{10}$.

Control of the effectivity of the disinfectant suppression activity

- Viral quantification of Poliovirus type 1 after 30 minutes on bath ice without exposing the virus to the test sample ..... $\log 10^{-7.41}$
- Viral quantification of Poliovirus type 1 exposing the virus to the test sample and incubated 30 minutes on ice bath ..... $\log 10^{-6.99}$

- Viral quantification of Adenovirus type 5 after 30 minutes on bath ice without exposing the virus to the test sample ..... $\log 10^{-7.08}$
- Viral quantification of Adenovirus type 5 exposing the virus to the test sample and incubated 30 minutes on ice bath ..... $\log 10^{-6.83}$

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- Viral quantification of Murine Norovirus after 30 minutes on bath ice without exposing the virus to the test sample ..... $\log 10^{-8.25}$
- Viral quantification of Murine Norovirus exposing the virus to the test sample and incubated 30 minutes on ice bath ..... $\log 10^{-7.74}$

Note: The difference between decimal logarithm of titre without exposing the virus to the sample and of the test suspension should be ≤ 0.5.

Special remarks

- All controls and validation were between the basic limits.
- To be accepted the assay, at least one concentration of the product must show a log reduction equal or higher than 4 log, and at least one concentration must show a log reduction lower than 4 log.

9. Assay results

9.1 Description of the results under the requested test conditions

Virus of assay	Test concentrations, reduction obtained with the confidence interval of 95 % and virucidal activity		
	80%	50%	0.1%
Poliovirus type 1	$\geq 7.00 \pm 0.37$ $TCID_{50}$ Shows	2.84 ± 0.56 $TCID_{50}$ Does not show	0.01 ± 0.49 $TCID_{50}$ Does not show
Adenovirus type 5	$\geq 6.32 \pm 0.41$ $TCID_{50}$ Shows	5.07 ± 0.48 $TCID_{50}$ Shows	0.07 ± 0.48 $TCID_{50}$ Does not show
Murine Norovirus	$\geq 7.82 \pm 0.42$ $TCID_{50}$ Shows	5.58 ± 0.56 $TCID_{50}$ Shows	0.08 ± 0.54 $TCID_{50}$ Does not show

Virucidal activity exists when the titre of virus shows a reduction ≥ 4 log.
$TCID_{50}$: Tissue Culture Infectious Dose 50%.

9.2 Tables of results and graphics

See tables 1 to 6 and figures 1 to 3.

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ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 60362/23/ROBCH

Conclusion

The product **"Dezinfectant Universal "Bio-Dez"**, batch 60362/23/ROBCH, at **80%** concentration, under dirty conditions (bovine serum albumin 3 g/L and erythrocytes 3 mL/L), requested by the client and during 60 seconds of contact time and 20°C of temperature, **shows** activity against Poliovirus type 1, Adenovirus type 5 and Murine Norovirus, when the activity is assayed according with the **EN 14476: 2013 + A2: 2019 Standard.**

Therefore, the disinfectant tested **shows general virucidal activity** at **80%** concentration, when the activity is assayed according with the **EN 14476: 2013 + A2: 2019 Standard**.

Note 1: The results obtained correspond to the sample received in this laboratory.
Note 2: The information that depend on the information received from the client and are not facilitated by the same one, shown as "not indicated".

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ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 60362/23/ROBCH

Table 1. Results of activity of the test sample with Poliovirus type 1 (ATCC VR-192) under test conditions requested by the client.

Assay	Concen-tration	Interfering substance	Cytoto-xicity level	$\log_{10}$ TCID$_{50}$ after…				Reduction with the confidence interval of 95 %
				0 min	60 sec	30 min	60 min	
Test sample	80%	3 g/L BSA + 3 mL/L erythrocytes	0.50	-	0.50	-	-	≥ 7.00 ± 0.37
	50%		0.50	-	4.66	-	-	2.84 ± 0.56
	0.1%		0.50		7.49			0.01 ± 0.49
Virus control	NA	3 g/L BSA + 3 mL/L erythrocytes	NA	7.58	7.50	-	-	NA
Formaldehyde	0.7% (w:v)	NA	0.50	NR	NR	4.99	3.08	NA
Virus control formaldehyde	0.7% (w:v)	NA	NA	7.58	NR	NR	7.32	NA

Control of sensitivity of cells to virus (difference between decimal logarithm of titre using treated and untreated cells) ..... $\log10^{-0.58}$

Control of the effectiveness of the disinfectant suppression activity (difference between decimal logarithm of titre without exposing the virus to the sample and of the test suspension)..... $\log10^{-0.42}$

NA: not applicable; NR: not realized.
Times recommended by Standard for surfaces: maximum 5 or 60 minutes.
Times recommended by Standard for instruments: maximum 60 minutes.
Times recommended by Standard for Hygienic treatment of hands by friction and hygienic handwashing: between 30 or 120 seconds.
PBS: phosphate buffered saline; BSA: bovine serum albumin.
Virucidal activity exists when the titre of virus shows a reduction ≥ 4 log.

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ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 60362/23/ROBCH

Table 2. Results of the activity of the test sample, with Poliovirus type 1 (ATCC VR-192) (Assay of titration with 12 wells), under test conditions requested by the client.

Assay	Concen-tration	Interfering substance	Time of contact (sec/min)	Dilutions (log10)[a,b]									
				1	2	3	4	5	6	7	8	9	10
Test sample	80%	3 g/L BSA + 3 mL/L erythrocytes	60 sec	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR
	50%		60 sec	4444 4444 4444	4444 4444 4444	4444 4444 4444	3240 0403 4432	0002 3010 0020	0200 0000 0000	0000 0000 0000	NR	NR	NR
	0.1%		60 sec	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	3241 0344 3032	0000 0200 0001	0000 0000 0000	NR
Cytotoxicity	80%	3 g/L BSA + 3 mL/L erythrocytes	NA	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR
Virus control	NA	3 g/L BSA + 3 mL/L erythrocytes	0	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	3244 3021 3044	0000 0220 0003	0000 0000 0000	NR
			60 sec	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	3204 4310 0233	0010 0000 2020	0000 0000 0000	NR
Formal-dehyde	0.7% (w:v)	NA	30 min	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	0030 2004 4030	0000 0020 0000	0000 0000 0000	NR	NR	NR
			60 min	4444 4444 4444	4444 4444 4444	0302 2304 0002	0000 0000 0100	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR
Control of formaldehyde cytotoxicity	0.7% (w:v)	3 g/L BSA + 3 mL/L erythrocytes	NA	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR
Virus control formal-dehyde	0.7% (w:v)	NA	0	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	0321 0044 4342	1000 2000 3020	0000 0000 0000	0000 0000 0000
			60 min	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	0321 0404 4303	0000 2000 0020	0000 0000 0000	0000 0000 0000
Sensitivity control of cells to virus	NA	NA	Cells not treated	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCC0 CCCC CCCC	0CCC 0CC0 C0CC	0000 C00C 0000	NR
			Cells treated	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	0CCC CC00 C0CC	C000 C0CC 0C00	0000 0000 C000	NR
Effectiveness control of the disinfectant suppression activity	NA	3 g/L BSA + 3 mL/L erythrocytes	Without sample	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC 0CCC CC00	000C 0000 00C0	0000 0000 0000	NR
			With sample	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CC0C C0CC	C0C0 0CCC 0C0C	0000 C000 0000	0000 0000 0000	NR

a): 1 to 4, virus present and grade of cytopathic effect in 12 units of cellular culture, or grade of cellular lesions in the cytotoxicity assay.
C = cytopathic effect with presence of virus (in this case and according to Standard does not take into account the degree of cytopathic effect only, the presence or absence of the same).
0 = no virus present or absence of cellular lesions in the cytotoxicity assay; NA: not applicable; NR: not realized; BSA: Bovine serum albumin; PBS: phosphate buffered saline.
sec: seconds; min: minutes;

ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 60362/23/ROBCH

Table 3. Results of activity of the test sample with Adenovirus type 5 (ATCC VR-5), under test conditions requested by the client.

Assay	Concen-tration	Interfering substance	Cytoto-xicity level	log_{10} $TCID_{50}$ after…				Reduction with the confidence interval of 95 %
				0 min	60 sec	30 min	60 Min	
Test sample	80%	3 g/L BSA + 3 mL/L erythrocytes	0.50	-	0.50	-	-	≥ 6.32 ± 0.41
	50%		0.50	-	1.75	-	-	5.07 ± 0.48
	0.1%		0.50	-	6.75	-	-	0.07 ± 0.48
Virus control	NA	3 g/L BSA + 3 mL/L erythrocytes	NA	6.91	6.82	-	-	NA
Formaldehyde	0.7% (w:v)	NA	0.50	NR	NR	3.49	2.75	NA
Virus control formaldehyde	0.7% (w:v)	NA	NA	7.16	NR	NR	6.98	NA

Control of sensitivity of cells to virus (difference between decimal logarithm of titre using treated and untreated cells) ..... $log10^{-0.67}$
Control of the effectiveness of the disinfectant suppression activity (difference between decimal logarithm of titre without exposing the virus to the sample and of the test suspension)..... $log10^{-0.25}$

NA: not applicable; NR: not realized.
Times recommended by Standard for surfaces: maximum 5 or 60 minutes.
Times recommended by Standard for instruments: maximum 60 minutes.
Times recommended by Standard for Hygienic treatment of hands by friction and hygienic handwashing: between 30 or 120 seconds.
PBS: phosphate buffered saline; BSA: bovine serum albumin.
Virucidal activity exists when the titre of virus shows a reduction ≥ 4 log.

ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 60362/23/ROBCH

Table 4. Results of the activity of the test sample, with Adenovirus type 5 (ATCC VR-5) (Assay of titration with 12 wells), under test conditions requested by the client.

Assay	Concen-tration	Interfering substance	Time of contact (sec/min)	Dilutions (log10)[a,b]									
				1	2	3	4	5	6	7	8	9	10
Test sample	80%	3 g/L BSA + 3 mL/L erythrocytes	60 sec	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR
	50%		60 sec	4433 2113 4443	0010 3002 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR
	0.1%		60 sec	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4433 1234 4433	0003 1000 2000	0000 0000 0000	NR	NR
Cytotoxicity	80%	3 g/L BSA + 3 mL/L erythrocytes	NA	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR
Virus control	NA	3 g/L BSA + 3 mL/L erythrocytes	0	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	3244 4302 3042	2004 0423 0001	0100 0000 0000	NR	NR
			60 sec	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	3201 4443 3440	0023 0102 0200	0000 0000 0001	NR	NR
Formal-dehyde	0.7% (w:v)	NA	30 min	4444 4444 4444	4444 4444 4444	3402 0303 2033	0001 2000 1000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR
			60 min	4444 4444 4444	3334 2444 3442	0202 0010 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR
Control of formal-dehyde cytotoxicity	0.7% (w:v)	3 g/L BSA + 3 mL/L erythrocytes	NA	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR
Virus control formal-dehyde	0.7% (w:v)	NA	0	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	0402 3030 4040	0000 0010 0020	0000 0000 0000	0000 0000 0000
			60 min	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4344 4340 2433	4020 0200 3200	0000 0010 0010	0000 0000 0000	0000 0000 0000
Sensitivity control of cells to virus	NA	NA	Cells not treated	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	0CCC CCC0 CC0C	0000 0C00 000C	NR	NR
			Cells treated	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC C0CC CC0C	0C00 CC00 0C00	0000 000C 0000	NR	NR
Effectiveness control of the disinfectant suppression activity	NA	3 g/L BSA + 3 mL/L erythrocytes	Without sample	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC C0C0 CCCC	C0C0 CC0C 00C0	000C C000 0C00	NR	NR
			With sample	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	00CC 0C00 00C0	0000 0000 0000	NR	NR

a): 1 to 4, virus present and grade of cytopathic effect in 12 units of cellular culture, or grade of cellular lesions in the cytotoxicity assay.
C = cytopathic effect with presence of virus (in this case and according to Standard does not take into account the degree of cytopathic effect only, the presence or absence of the same).
0 = no virus present or absence of cellular lesions in the cytotoxicity assay; NA: not applicable; NR: not realized; BSA: Bovine serum albumin; PBS: phosphate buffered saline.
sec: seconds; min: minutes.

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ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 60362/23/ROBCH

Table 5. Results of activity of the test sample, with Murine Norovirus, strain S99 Berlin, under test conditions requested by the client.

Assay	Concen-tration	Interfering substance	Cytoto-xicity level	$\log_{10}$ TCID$_{50}$ after…				Reduction with the confidence interval of 95 %
				0 min	60 sec	30 min	60 min	
Test sample	80%	3 g/L BSA + 3 mL/L erythrocytes	0.50	-	0.50	-	-	≥ 7.82 ± 0.42
	50%		0.50	-	2.74	-	-	5.58 ± 0.56
	0.1%		0.50	-	8.24	-	-	0.08 ± 0.54
Virus control	NA	3 g/L BSA + 3 mL/L erythrocytes	NA	8.41	8.32	-	-	NA
Formaldehyde	0.7% (w:v)	NA	0.50	NR	NR	5.74	4.99	NA
Virus control formaldehyde	0.7% (w:v)	NA	NA	8.50	NR	NR	8.32	NA

Control of sensitivity of cells to virus (difference between decimal logarithm of titre using treated and untreated cells) ..... $\log10^{-0.67}$

Control of the effectiveness of the disinfectant suppression activity (difference between decimal logarithm of titre without exposing the virus to the sample and of the test suspension)..... $\log10^{-0.43}$

NA: not applicable; NR: not realized.
Times recommended by Standard for surfaces: maximum 5 or 60 minutes.
Times recommended by Standard for instruments: maximum 60 minutes.
Times recommended by Standard for Hygienic treatment of hands by friction and hygienic handwashing: between 30 or 120 seconds.
PBS: phosphate buffered saline; BSA: bovine serum albumin.
Virucidal activity exists when the titre of virus shows a reduction ≥ 4 log.

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ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 60362/23/ROBCH

Table 6. Results of the activity of the test sample, with Murine Norovirus strain S99 Berlin (Assay of titration with 12 wells), under test conditions requested by the client.

Assay	Concen-tration	Interfering substance	Time of contact (sec/min)	Dilutions (log10)[a,b]									
				1	2	3	4	5	6	7	8	9	10
Test sample	80%	3 g/L BSA + 3 mL/L erythrocytes	60 sec	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR
	50%		60 sec	4444 4444 4444	3244 3020 2244	0020 0122 0030	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR
	0.1%		60 sec	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	0302 2010 3212	0000 0000 0002	NR
Cytotoxicity	80%	3 g/L BSA + 3 mL/L erythrocytes	NA	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR
Virus control	NA	3 g/L BSA + 3 mL/L erythrocytes	0	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	0323 0404 3302	0020 0000 0210	NR
			60 sec	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	3244 3321 2013	3213 0030 2203	0002 0200 0010	NR
Formal-dehyde	0.7% (w:v)	NA	30 min	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	3344 0334 4444	0200 0202 0100	0000 0000 0000	NR	NR	NR
			60 min	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	0030 4020 2200	0000 0100 0000	0000 0000 0000	NR	NR	NR
Control of formal-dehyde cytotoxicity	0.7% (w:v)	3 g/L BSA + 3 mL/L erythrocytes	NA	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR
Virus control formal-dehyde	0.7% (w:v)	NA	0	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	3042 4040 4433	0000 1000 0102	0000 0000 0000
			60 min	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4244 3330	2002 0302 2434	0000 0120 0100	0000 0000 0000
Sensitivity control of cells to virus	NA	NA	Cells not treated	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	0CCC CCCC 0CCC	CC00 000C 00C0	NR
			Cells treated	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CC0C CCC0 C0CC	C0CC 00CC C00C	0000 0C00 0C00	NR
Effectiveness control of the disinfectant suppression activity	NA	3 g/L BSA + 3 mL/L erythrocytes	Without sample	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	0CCC 00C0 0C0C	C000 00C0 C000	NR
			With sample	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC C0CC CCCC	0000 CC00 C0C0	0C00 0000 0000	NR

a): 1 to 4, virus present and grade of cytopathic effect in 12 units of cellular culture, or grade of cellular lesions in the cytotoxicity assay.
C = cytopathic effect with presence of virus (in this case and according to Standard does not take into account the degree of cytopathic effect only, the presence or absence of the same).
0 = no virus present or absence of cellular lesions in the cytotoxicity assay; NA: not applicable; NR: not realized; BSA: Bovine serum albumin; PBS: phosphate buffered saline.
Sec: seconds; min: minutes.

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Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 60362/23/ROBCH

Figure 1. Results of the activity of the test sample under test conditions requested by the client with Poliovirus type 1 (ATCC VR-192).

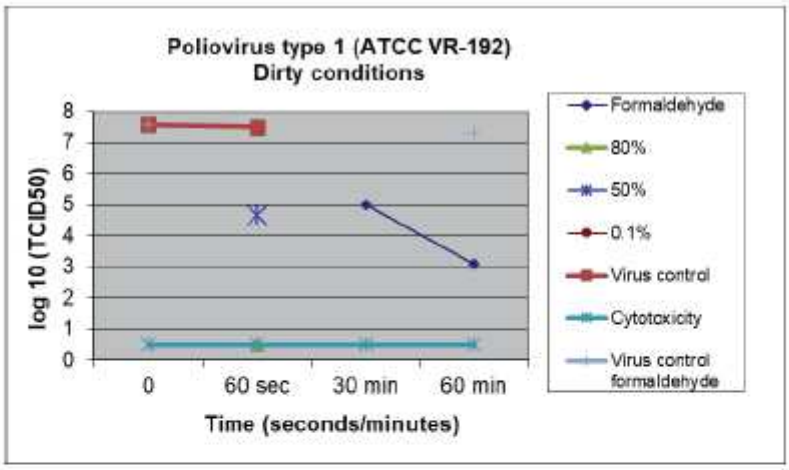
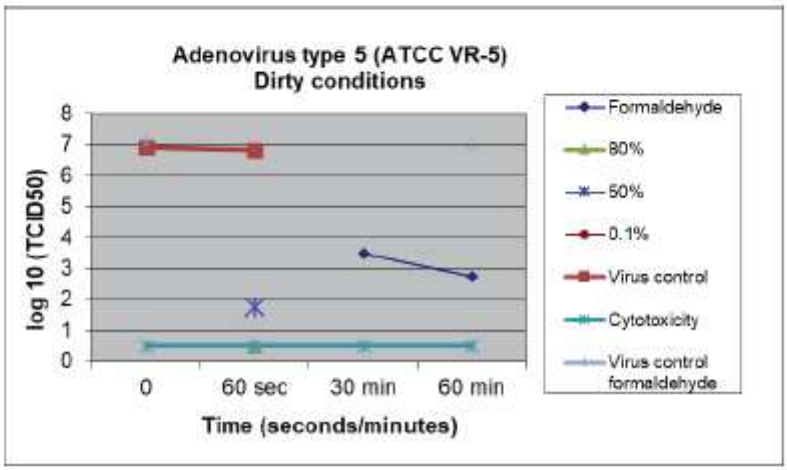


Figure 2. Results of the activity of the test sample under test conditions requested by the client with Adenovirus type 5 (ATCC VR-5).



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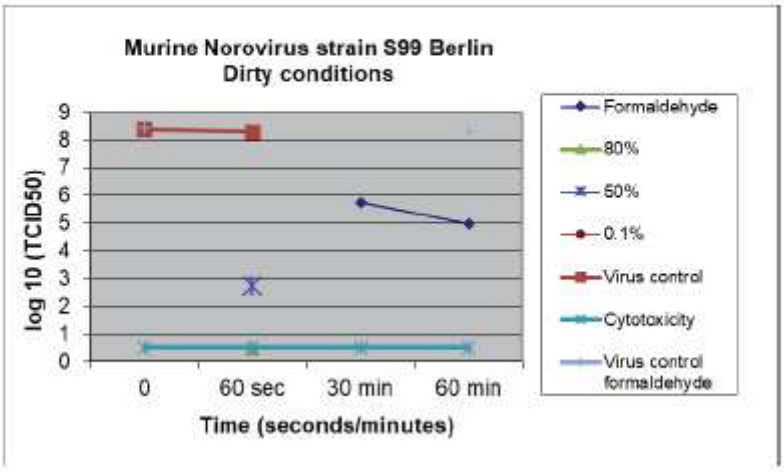
ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 60362/23/ROBCH

Figure 3. Results of the activity of the test sample under test conditions requested by the client with Murine Norovirus strain S99 Berlin.



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HAMILTON ROMANIA

REPORT OF ANALYSIS No. 16417/22/ROBCH

Client	Sample number:
ECOCHIM-GRUP SRL OR. OTACI, STR. VOITOVICI 21 2059 CHIȘINĂU	**16417/22/ROBCH** Sample description *(according to declaration of Client)* **Dezinfectant Universal "Bio-Dez"** **Lot: FABR.08.2020** **Data fabricatie: -** **Data expirarii: 18.02.2025** **Data prelevarii:18.02.2022** **Cantitate prelevata: 3 x 500 ml** **Responsabil prelevare: Crestinov Alexandr** **Ora receptiei probei: -** **Temperatura receptie proba: 15°C** **Sample condition with no objections**
Sample received: **01.03.2022** Tests performed: **01.03.2022** Tests completed: **13.04.2022** Report dated: **13.04.2022**	**Order of 01.03.2022** Sampling and delivery were carried out by client.

Test	Method	Unit	Result
# * Chemical disinfectants and antiseptics. Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the medical area. Test method and requirements (phase 2, step 2)	UNE-EN 14561:2007	-	Test method performed by the subcontractor; the results are taken in full from the test report No D/22/ B0135, issued by the subcontractor. The results of the analysis are listed starting with enclosure No1 to report of analysis.

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Authorized by: Mariana Ilinca, Manager of Microbiological Laboratory
Approved by: Alina-Roxana Mihai, General Manager *(Approved with qualified electronic signature)*

Laboratory: Bucuresti 041914, sos. Berceni nr.8

* Test method accredited # Test performed by external provider
ø Non accredited methods

PGL 09 F 01 Ed. 1 Rev. 2

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ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 16417/22/ROBCH

A) IDENTYFICATION OF THE SAMPLE	
Name of the product/Details about the product	**Dezinfectant Universal "Bio-Dez"** Expiration date: 18.02.2025 Manufacturer(supplier): Ecochim-Grup S.R.L. Store condition: Dry, without sun, 5-25ºC. Condition of use: Chemical disinfection of certain instrument surfaces in the medical area.
Active(s) Substance(s) and its concentration(s)	Ethyl alcool 72-76%, CAS 64-17-5 and CE 200-578-6 Benzalkonium chloride 0.024- 0.029%, CAS 68424-85-1 and CE 270-325-2 Methylthionibium chloride 0.00024%, CAS 61-73-4 and 200-515-2.
Concentration ordered for the assay	Pure (100%)
B) TEST METHOD	
Performed in accredited subcontracted partner laboratory: Scope of Accreditation Nr. 648/LE1286 Report D/22/B0135 Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the medical area (phase 2, step 2), with the product D**ezinfectant Universal "Bio-Dez**". (UNE-EN 14561: 2007 Standard)	UNE-EN 14561 : 2007. Chemical disinfectants and antiseptics. Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the medical area. Test method and requirements (phase 2, step2). AENOR.
Testing method	DESIN-1032-b //EN 14561: 2007
Methods of assay and its validation UNE-EN 14561: 2007 Standard	
Method	Dilution-neutralization.
Neutralizer	Tryptone 5 g/L, yeast extract, 2.5 g/L, dextrose 10 g/L, sodium thioglycolate 1 g/L, sodium thiosulfate 1 g/L, sodium bisulphite 2.5 g/L, soya lecithin 7 g/L, polysorbate-80 5 g/L, glycine 1 g/L, l-histidine 1 g/L and saponin 30 g/L.
C) INFORMATION ABOUT SAMPLE RECEPTION	
Date of reception of the sample	2022/03/04
Date of reception of order with test conditions	2022/03/01.
Aspect of the received product	Blue transparent liquid in plastic package.
D) EXPERIMENTAL CONDITIONS	
Assay period	2022/03/23 to 2022/03/28
Solvent of the product used in the assay	Sterile distilled water
Product concentrations for the assay	Pure (100%), 50% and 0.1%.
Aspect of the dilutions of the product	Pure 100% and 50% blue liquid, 0.1% transparent liquid.
Contact time	60 seconds
Assay temperature	20°C ± 1°C
Interfering substance	Bovine serum albumin 3 g/L plus erythrocytes 3 mL/L.
Stability of the mixture (interfering substance and product diluted in sterile hard water/distilled water)	Stable
Incubation temperature	+36°C ± 1°C
Identification of the strains used:	− *Pseudomonas aeruginosa* (CECT 116 = ATCC 15442). − *Staphylococcus aureus* (CECT 239 = ATCC 6538). − *Enterococcus hirae* (CECT 4081 = ATCC 10541).

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ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 16417/22/ROBCH

Results of the assay

- Assay of validation ..... See tables 1, 2, 3, 5, 6, 7, 9, 10 and 11.
- Evaluation of bactericidal activity ..... See tables 4, 8 and 12.
- Number of replicates per assay organism ... 1.

Special remarks

- All controls and validation were between the basic limits.
- At least one concentration of the sample showed a log reduction lower than 5 log.
- At least one concentration of the sample showed a log reduction higher than 5 log.
- There was not any precipitation during the assay procedure (the assay mixtures were homogeneous).

Conclusion

The product **Dezinfectant Universal "Bio-Dez"**, batch not indicated, when is pure (100%), **shows bactericidal activity** after 60 seconds at 20ºC ±1ºC, under dirty conditions (bovine serum albumin 3 g/L plus erythrocytes 3 mL/L), for *Pseudomonas aeruginosa* (CECT 116 = ATCC 15442), *Staphylococcus aureus* (CECT 239 = ATCC 6538) and *Enterococcus hirae* (CECT 4081 = ATCC 10541), when tested as required by **UNE-EN 14561: 2007 Standard.**

Note: The results obtained correspond to the sample received in the laboratory.

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ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 16417/22/ROBCH

Results of the assay with *Pseudomonas aeruginosa* (CECT 116 = ATCC 15442).

Seeding: Pour plates. No. of plates: 1/mL. Drying time of the slide: 15 minutes.

Table 1.-Validation and controls.

Suspension of validation (Nv_0)				Control of experimental conditions (A)				Control of the neutralizer (B)				Validation of the method (C) Sample concentration: Pure			
Counts per plate		Vc_1	Vc_2	Counts per plate		Vc_1	Vc_2	Counts per plate		Vc_1	Vc_2	Counts per plate		Vc_1	Vc_2
42	40	42	40	30	31	30	31	35	37	35	37	31	34	31	34
$30 \le X$ of $Nv_0 \le 160$? $X = 41$				X of A is ≥ 0.5 x X of Nv_0? $X = 30.5$				X of B is ≥ 0.5 x X of Nv_0? $X = 36$				X of C is ≥ 0.5 x X of Nv_0? $X = 32.5$			
Yes				Yes				Yes				Yes			

Table 2.-Suspension of the assay.

	N	Counts per plate		Vc_1	Vc_2	
Suspension of assay (N)	10^{-7}	158	153	158	153	$Xwm = 1.56 \times 10^9$ $\lg N = 9.19$ $9.17 \le \lg N \le 9.7$? Yes
	10^{-8}	15	16	15	16	

Table 3.-Water control.

	Nw	Counts per plate		Vc_1	Vc_2	
Water control (Nw)	10^{-5}	16	15	16	15	$Xwm \times 10 = 1.55 \times 10^7$ $\lg Nw = 7.19$ $7.15 \le \lg Nw \le (\lg N\text{-}1.3)$? Yes

Table 4.-Results of the activity assays with the sample.

Sample concentration (%)	Dilution	Counts per plate		Vc_1	Vc_2	Lg Na = lg (X o Xwm)+1	Lg R (lgNw = 7.19)	Time of contact (sec)
Pure 100%	10^0	0	0	<14	<14	<2.15	>5.04	60
	10^{-1}	0	0	<14	<14			
	10^{-2}	0	0	<14	<14			
	10^{-3}	0	0	<14	<14			
50%	10^0	>330	>330	>330	>330	3.49	3.70	60
	10^{-1}	30	32	30	32			
	10^{-2}	3	3	<14	<14			
	10^{-3}	0	0	<14	<14			
0.1%	10^0	>330	>330	>330	>330	> 6.52	<0.67	60
	10^{-1}	>330	>330	>330	>330			
	10^{-2}	>330	>330	>330	>330			
	10^{-3}	>330	>330	>330	>330			

*Test method accredited # Test performed by subcontractor. Ø Non accredited methods.

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ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 16417/22/ROBCH

Results of the assay with *Staphylococcus aureus* (CECT 239 = ATCC 6538).
Seeding: Pour plates. No. of plates: 1/mL; Drying time of the slide: 18 minutes.

Table 5.-Validation and controls.

Suspension of validation (Nv_0)				Control of experimental conditions (A)				Control of the neutralizer (B)				Validation of the method (C) Sample concentration: Pure			
Counts per plate		Vc_1	Vc_2	Counts per plate		Vc_1	Vc_2	Counts per plate		Vc_1	Vc_2	Counts per plate		Vc_1	Vc_2
48	51	48	51	39	40	39	40	28	28	28	28	30	28	30	28
$30 \le X$ of $Nv_0 \le 160$? $X = 49.5$				X of A is ≥ 0.5 x X of Nv_0? $X = 39.5$				X of B is ≥ 0.5 x X of Nv_0? $X = 28$				X of C is ≥ 0.5 x X of Nv_0? $X = 29$			
Yes				Yes				Yes				Yes			

Table 6.-Suspension of the assay.

	N	Counts per plate		Vc_1	Vc_2	
Suspension of assay (N)	10^{-7}	202	199	202	199	$Xwm = 2.00 \times 10^9$ lg N= 9.30 $9.17 \le \lg N \le 9.7$? Yes
	10^{-8}	19	19	19	19	

Table 7.-Water control.

	Nw	Counts per plate		Vc_1	Vc_2	
Water control (Nw)	10^{-5}	32	35	32	35	$Xwm \times 10 = 3.35 \times 10^7$ lg Nw= 7.53 $7.15 \le \lg Nw \le (\lg N\text{-}1.3)$? Yes

Table 8.-Results of the activity assays with the sample.

Sample concentration (%)	Dilution	Counts per plate		Vc_1	Vc_2	Lg Na = lg (X o Xwm)+1	Lg R (lgNw = 7.53)	Time of contact (sec)
Pure 100%	10^0	0	0	<14	<14	<2.15	>5.38	60
	10^{-1}	0	0	<14	<14			
	10^{-2}	0	0	<14	<14			
	10^{-3}	0	0	<14	<14			
50%	10^0	>330	>330	>330	>330	4.33	3.20	60
	10^{-1}	210	215	210	215			
	10^{-2}	20	22	20	22			
	10^{-3}	2	1	<14	<14			
0.1%	10^0	>330	>330	>330	>330	> 6.52	<1.01	60
	10^{-1}	>330	>330	>330	>330			
	10^{-2}	>330	>330	>330	>330			
	10^{-3}	>330	>330	>330	>330			

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ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 16417/22/ROBCH

Results of the assay with *Enterococcus hirae* (CECT 4081 = ATCC 10541).

Seeding: Pour plates. No. of plates: 1/mL; Drying time of the slide: 16 minutes.

Table 9.-Validation and controls.

Suspension of validation (Nv_0)				Control of experimental conditions (A)				Control of the neutralizer (B)				Validation of the method (C) Sample concentration: Pure			
Counts per plate		Vc_1	Vc_2	Counts per plate		Vc_1	Vc_2	Counts per plate		Vc_1	Vc_2	Counts per plate		Vc_1	Vc_2
46	47	46	47	29	28	29	28	31	30	31	30	27	28	27	28
$30 \leq X$ of $Nv_0 \leq 160$? $X = 46.5$				X of A is ≥ 0.5 x X of Nv_0? $X = 28.5$				X of B is ≥ 0.5 x X of Nv_0? $X = 30.5$				X of C is ≥ 0.5 x X of Nv_0? X = 27.5			
Yes				Yes				Yes				Yes			

Table 10.-Suspension of the assay.

	N	Counts per plate		Vc_1	Vc_2	
Suspension of assay (N)	10^{-7}	189	185	189	185	$Xwm = 1.86 \times 10^9$ lg N= 9.27 $9.17 \leq \lg N \leq 9.7$? Yes
	10^{-8}	17	18	17	18	

Table 11.-Water control.

	Nw	Counts per plate		Vc_1	Vc_2	
Water control (Nw)	10^{-5}	18	19	18	19	$Xwm \times 10 = 1.85 \times 10^7$ lg Nw= 7.27 $7.15 \leq \lg Nw \leq (\lg N\text{-}1.3)$? Yes

Table 12.-Results of the activity assays with the sample.

Sample concentration (%)	Dilution	Counts per plate		Vc_1	Vc_2	Lg Na = lg (X o Xwm)+1	Lg R (lgNw = 7.27)	Time of contact (sec)
Pure 100%	10^0	0	0	<14	<14	<2.15	>5.12	60
	10^{-1}	0	0	<14	<14			
	10^{-2}	0	0	<14	<14			
	10^{-3}	0	0	<14	<14			
50%	10^0	>330	>330	>330	>330	4.77	2.50	60
	10^{-1}	>330	>330	>330	>330			
	10^{-2}	57	60	57	60			
	10^{-3}	5	6	<14	<14			
0.1%	10^0	>330	>330	>330	>330	> 6.52	<0.75	60
	10^{-1}	>330	>330	>330	>330			
	10^{-2}	>330	>330	>330	>330			
	10^{-3}	>330	>330	>330	>330			

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Date: 05.04.2022
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Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 16417/22/ROBCH

Explanations:

Vc = Count per mL (one or more plates).
X= mean of Vc_1 and Vc_2.
Xwm = ponderated mean of *X*;
R (reduction) = (lg *R* = log *Nw* – log *Na*).
If *Na* < 140, log *R* = > [log *Nw* – 2,15]

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REPORT OF ANALYSIS No. 92190/22/ROBCH

Client	Sample number:
ECOCHIM-GRUP SRL OR. OTACI, STR. VOITOVICI 21 2059 CHIȘINĂU	**92190/22/ROBCH** Sample description *(according to declaration of Client)* **Dezinfectant Universal "Bio-Dez"** **Lot/Batch: -** **Production date: 21.09.2022** **Expiration date: 21.09.2025** **Sampling date: 29.09.2022** **Sampling quantity: 1x 500ml** **Sample temperature: 17°C** **Reception hour: 12:30** **Responsible for sampling: Crestinov Alexandr** **Sample condition with no objections**
Sample received: **18.10.2022** Tests performed: **19.10.2022** Tests completed: **09.12.2022** Report dated: **09.12.2022**	**Order of 18.10.2022** Sampling and delivery were carried out by client.

Test	Method	Unit	Result
# * Chemical disinfectants and antiseptics. Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the medical area. Test method and requirements (phase 2, step 2)	EN 14562:2007	-	Test method performed by the subcontractor; the results are taken in full from the test report No D/22/ B0669, issued by the subcontractor. The results of the analysis are listed starting with enclosure No1 to report of analysis.

Elaborated by: Mariana Ilinca, Manager of Microbiological Laboratory
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Laboratory: Bucuresti 041914, sos. Berceni nr.8

* Test method accredited # Test performed by external provider
ø Non accredited methods

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A.N.S.V.S.A. Authorization no 115 from 18.06.2018

ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 92190/22/ROBCH

A) IDENTYFICATION OF THE SAMPLE	
Name of the product/Details about the product	**Dezinfectant Universal "Bio-Dez".** Manufacturer(supplier): Ecochim-Grup. Store condition: Dry, without sun, 5-25 Celsius degree. Condition of use: PT2 product in the medical area. Solvent of the product recommended by the manufacturer: Undiluted.
Active(s) Substance(s) and its concentration(s)	Ethyl alcool 72-76%, CAS 64-17-5 and CE 200-578-6; Benzalkonium chloride 0.024-0.029%, CAS 68424-85-1 and CE 270-325-2; Methylthionibium chloride 0.00024%, CAS 61-73-4 and 200-515-2.
Concentration ordered for the assay	Ready to use (100%).
B) TEST METHOD	
Performed in accredited subcontracted partner laboratory: Scope of Accreditation Nr. 648/LE1286 Report D/22/B0669 Quantitative carrier test for evaluation of the fungicidal activity of chemical disinfectants for instruments used in the medical area (phase 2, step 2), with the product "Dezinfectant Universal "Bio-Dez". (EN 14562: 2007 Standard)	EN 14562: 2007. Chemical disinfectants and antiseptics – Quantitative carrier test for the evaluation of the antifungal or yeasticidal activity of chemical disinfectants for instruments used in the medical area. Test methods and requirements (phase 2/step 2).
Testing method	DESIN-1059-b // EN 14562: 2007
Methods of assay and its validation EN 14562: 2007 Standard	
Method	Dilution-neutralization.
Neutralizer	Tryptone 5 g/L, yeast extract, 2.5 g/L, dextrose 10 g/L, sodium thioglycolate 1 g/L, sodium thiosulfate 1 g/L, sodium bisulphite 2.5 g/L, soya lecithin 7 g/L, polysorbate-80 5 g/L, glycine 1 g/L, l-histidine 1 g/L and saponin 30 g/L.
C) INFORMATION ABOUT SAMPLE RECEPTION	
Date of reception of the sample	2022/10/19
Date of reception of order with test conditions	2022/10/24.
Aspect of the received product	Blue liquid in a plastic package.
D) EXPERIMENTAL CONDITIONS	
Assay period	2022/11/15 to 2022/11/25.
Solvent of the product used in the assay	Sterile distilled water
Product concentrations for the assay	100%, 50% and 0.1%.
Aspect of the dilutions of the product	100% and 50%: Blue liquid; 0.1%: Transparent liquid
Contact time	90 seconds
Assay temperature	20°C ± 1°C
Interfering substance	Bovine serum albumin 3 g/L + 3 ml/L erythrocytes
Stability of the mixture (interfering substance and product diluted in sterile hard water/distilled water)	Stable
Incubation temperature	+30ºC □ 1ºC
Drying time of the slides	*C.albicans*: 35 minutes. *A.brasiliensis*: 37 minutes
Identification of the strains used:	*-Aspergillus brasiliensis (CECT 2574 = ATCC 16404).* *-Candida albicans (CECT 1394 = ATCC 10231).*

*Test method accredited # Test performed by subcontractor. Ø Non accredited methods.
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Date: 08.12.2022
Authorized by: Mariana Ilinca, Manager of Microbiological laboratory
Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 92190/22/ROBCH

Results of the assay

- Controls and validation ..... See tables 1, 2, 3, 5, 6 and 7.
- Evaluation of fungicidal activity ..... See tables 4 and 8.
- Number of replicates per assay organism ..... 1.

Special remarks

- All controls and validation were between the basic limits.
- At least one concentration of the sample showed a log reduction lower than 4 log.
- At least one concentration of the sample showed a log reduction higher than 4 log.
- There was not any precipitation during the assay procedure (the assay mixtures were homogeneous).
- The test meets the criteria of the BPR Guidance for PT2 products in the medical area

Conclusion

The product **"Dezinfectant Universal "Bio-Dez""**, batch 92190/22/robch, when it is pure (100%), concentration requested by the client, **shows fungicidal activity** after 90 seconds at 20ºC ±1ºC, under dirty conditions (bovine serum albumin 3 g/L + 3 ml/L erythrocytes), for the reference strains *Aspergillus brasiliensis* (CECT 2574 = ATCC 16404) and *Candida albicans* (CECT 1394 = ATCC 10231), when tested as required by **EN 14562: 2007 Standard.**

Note: The results obtained correspond to the sample received in the laboratory.

Use of the ENAC mark: The ENAC *"mark"* can only be used by the holder of the accreditation. Its use in packaging, installations, shop windows, advertising or other documentation format other than that issued by the accredited entity (IVAMI) is not allowed.

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ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 92190/22/ROBCH

Results of the assay with *Aspergillus brasiliensis* (CECT 2574 = ATCC 16404)

Drying time of the slide: 37 minutes (no longer than 60 minutes).

Seeding: Pour plates; No. of plates: 4/mL

Table 1.-Validation and controls

Suspension of validation (Nv_0)				**Control of experimental conditions (*A*)**				**Control of the neutralizer (*B*)**				**Validation of the method (*C*) Sample concentration: 100%**			
Counts per plate		Vc_1	Vc_2	**Counts per plate**		Vc_1	Vc_2	**Counts per plate**		Vc_1	Vc_2	**Counts per plate**		Vc_1	Vc_2
12+10+ 12+11	11+11+ 10+10	45	42	9+12+ 10+10	9+9 +11+10	41	39	10+10+ 9+9	11+10+ 9+9	38	39	8+7 +8+8	8+9 +8+8	31	33
$30 \le X$ of $Nv_0 \le 160$? $X = 43.5$				X of A is ≥ 0.5 x X of Nv_0? $X = 40$				X of B is ≥ 0.5 x X of Nv_0? $X = 38.5$				X of C is ≥ 0.5 x X of Nv_0? $X = 32$			
Yes				Yes				Yes				Yes			

Table 2.-Suspension of the assay

Suspension of assay (*N*)	N	**Counts per plate**		Vc_1	Vc_2	$Xwm = 2.52 \times 10^8$ $\lg N = 8.40$ ¿$8.17 \le \lg N \le 8.7$? Yes
	10^{-6}	66+52+53 +76	60+59+66+ 73	247	258	
	10^{-7}	6+6+6+6	6+7+6+7	24	26	

Table 3.-Water control

Water control (Nw)	Nw	**Counts per plate**		Vc_1	Vc_2	$Xwm \times 10 = 6.80 \times 10^6$ $\lg Nw = 6.83$ $6.15 \le \lg Nw \le (\lg N\text{-}1.3)$? Yes
	10^{-4}	18+17+17 +16	18+16+18+ 16	68	68	

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ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 92190/22/ROBCH

Table 4.-Results of the activity assays with the sample

Sample concentration (%)	Dilution	Counts per plate		Vc_1	Vc_2	Lg Na = lg (X o Xwm) +1	Lg R (lgNw = 6.83)	Time of contact (seconds)
100%	10^0	0+0+0+0	0+0+0+0	<14	<14	<2.15	>4.68	90
	10^{-1}	0+0+0+0	0+0+0+0	<14	<14			
	10^{-2}	0+0+0+0	0+0+0+0	<14	<14			
	10^{-3}	0+0+0+0	0+0+0+0	<14	<14			
50%	10^0	>165+>165+ >165+>165	>165+>165+ >165+>165	>660	>660	5.42	1.41	90
	10^{-1}	>165+>165+ >165+>165	>165+>165+ >165+>165	>660	>660			
	10^{-2}	65+70 +69+65	71+65 +61+66	269	263			
	10^{-3}	6+5+6+6	7+6+5+6	23	24			
0.1%	10^0	>165+>165+ >165+>165	>165+>165+ >165+>165	>660	>660	>6.82	<0.01	90
	10^{-1}	>165+>165+ >165+>165	>165+>165+ >165+>165	>660	>660			
	10^{-2}	>165+>165+ >165+>165	>165+>165+ >165+>165	>660	>660			
	10^{-3}	>165+>165+ >165+>165	>165+>165+ >165+>165	>660	>660			

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Results of the assay with *Candida albicans* (CECT 1394 = ATCC 10231)

Drying time of the slide: 35 minutes (no longer than 60 minutes).

Seeding: Pour plates; No. of plates: 1/mL

Table 5.-Validation and controls

Suspension of validation (Nv_0)				Control of experimental conditions (A)				Control of the neutralizer (B)				Validation of the method (C) Sample concentration: 100%			
Counts per plate		Vc_1	Vc_2	Counts per plate		Vc_1	Vc_2	Counts per plate		Vc_1	Vc_2	Counts per plate		Vc_1	Vc_2
40	37	40	37	35	33	35	33	30	33	30	33	29	31	29	31
$30 \le X$ of $Nv_0 \le 160$? $X = 38.5$				X of A is ≥ 0.5 x X of Nv_0? $X = 34$				X of B is ≥ 0.5 x X of Nv_0? $X = 31.5$				X of C is ≥ 0.5 x X of Nv_0? $X = 30$			
Yes				Yes				Yes				Yes			

Table 6.-Suspension of the assay

Suspension of assay (N)	N	Counts per plate		Vc_1	Vc_2	$Xwm = 1.61 \times 10^8$ $\lg N = 8.21$ $8.17 \le \lg N \le 8.7$?
	10^{-6}	168	156	168	156	
	10^{-7}	16	15	16	15	Yes

Table 7.-Water control

Water control (Nw)	Nw	Counts per plate		Vc_1	Vc_2	$Xwm \times 10 = 5.25 \times 10^6$ $\lg Nw = 6.72$ $6.15 \le \lg N - 1.3$? Yes
	10^{-4}	53	52	53	52	

Table 8.-Results of the activity assays with the sample

Sample concentration (%)	Dilution	Counts per plate		Vc_1	Vc_2	Lg Na = lg (X o Xwm) +1	Lg R (lgNw = 6.72)	Time of contact (seconds)
100%	10^0	0	0	<14	<14	<2.15	>4.57	90
	10^{-1}	0	0	<14	<14			
	10^{-2}	0	0	<14	<14			
	10^{-3}	0	0	<14	<14			
50%	10^0	0	0	<14	<14	<2.15	>4.57	90
	10^{-1}	0	0	<14	<14			
	10^{-2}	0	0	<14	<14			
	10^{-3}	0	0	<14	<14			
0.1%	10^0	>330	>330	>330	>330	5.93	0.79	90
	10^{-1}	>330	>330	>330	>330			
	10^{-2}	>330	>330	>330	>330			
	10^{-3}	86	84	86	84			

*Test method accredited # Test performed by subcontractor. Ø Non accredited methods.

Date: 08.12.2022
Authorized by: Mariana Ilinca, Manager of Microbiological laboratory
Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 92190/22/ROBCH

Explanations:

Vc = Count per mL (one or more plates).

X= mean of Vc_1 and Vc_2.

Xwm = Weighted mean of *X*; ***R*** (reduction) = (lg ***R*** = log *Nw* – log *Na*).

If *Na* < 140, log ***R*** = > [log *Nw* – 2.15]

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REPORT OF ANALYSIS No. 16418/22/ROBCH

Client	Sample number:
ECOCHIM-GRUP SRL OR. OTACI, STR. VOITOVICI 21 2059 CHIȘINĂU	**16418/22/ROBCH** Sample description *(according to declaration of Client)* **Dezinfectant Universal "Bio-Dez"** **Lot: FABR.08.2020** **Data fabricatie: -** **Data expirarii: 18.02.2025** **Data prelevarii:18.02.2022** **Cantitate prelevata: 3 x 500 ml** **Responsabil prelevare: Crestinov Alexandr** **Ora receptiei probei: -** **Temperatura receptie proba: 15°C** **Sample condition with no objections**
Sample received: **01.03.2022** Tests performed: **01.03.2022** Tests completed: **16.06.2022** Report dated: **16.06.2022**	**Order of 01.03.2022** Sampling and delivery were carried out by client.

Test	Method	Unit	Result
# * Quantitative carrier test for the evaluation of mycobactericidal or tuberculocidal activity of chemical disinfectants and antiseptics used in the medical area	UNE-EN 14563:2009	-	Test method performed by the subcontractor; the results are taken in full from the test report No D/22/ B0134, issued by the subcontractor. The results of the analysis are listed starting with enclosure No1 to report of analysis.

Elaborated by: Mariana Ilinca, Manager of Microbiological Laboratory
Authorized by: Mariana Ilinca, Manager of Microbiological Laboratory
Approved by: Alina-Roxana Mihai, General Manager *(Approved with qualified electronic signature)*

Laboratory: Bucuresti 041914, sos. Berceni nr.8

* Test method accredited # Test performed by external provider
ø Non accredited methods

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ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 16418/22/ROBCH

A) IDENTYFICATION OF THE SAMPLE	
Name of the product/Details about the product	**Dezinfectant Universal "Bio-Dez"** Expiration date: 18.02.2025 Manufacturer(supplier): Ecochim-Grup S.R.L. Store condition: Dry, without sun, 5-25ºC. Condition of use: Chemical disinfection of certain instrument surfaces in the medical area.
Active(s) Substance(s) and its concentration(s)	Ethyl alcool 72-76%, CAS 64-17-5 and CE 200-578-6 Benzalkonium chloride 0.024- 0.029%, CAS 68424-85-1 and CE 270-325-2 Methylthionibium chloride 0.00024%, CAS 61-73-4 and 200-515-2.
Concentration ordered for the assay	Pure (100%)
B) TEST METHOD	
Performed in accredited subcontracted partner laboratory: Scope of Accreditation Nr. 648/LE1286 Report D/22/B0134 Quantitative carrier test for the evaluation of mycobactericidal and tuberculocidal activity of chemical disinfectants used for instruments in the medical area (phase 2, step 2), with the product **Dezinfectant Universal "Bio-Dez"**. (UNE-EN 14563 : 2009 Standard)	UNE-EN 14563: 2009. Chemical disinfectants and antiseptics. Quantitative carrier test for the evaluation of mycobactericidal or tuberculocidal activity of chemical disinfectants used for instruments in the medical area. Test method and requirements (phase 2, step 2).
Testing method	DESIN-1054-b //EN 14563: 2009
Methods of assay and its validation UNE-EN 14561: 2007 Standard	
Method	Dilution-neutralization.
Neutralizer	Tryptone 5 g/L, yeast extract, 2.5 g/L, dextrose 10 g/L, sodium thioglycolate 1 g/L, sodium thiosulfate 1 g/L, sodium bisulphite 2.5 g/L, soya lecithin 7 g/L, polysorbate-80 5 g/L, glycine 1 g/L, l-histidine 1 g/L and saponin 30 g/L.
C) INFORMATION ABOUT SAMPLE RECEPTION	
Date of reception of the sample	2022/03/04
Date of reception of order with test conditions	2022/03/01.
Aspect of the received product	Blue transparent liquid in plastic package.
D) EXPERIMENTAL CONDITIONS	
Assay period	2022/03/02 to 2022/04/13 (Including prior preparation of the strains).
Solvent of the product used in the assay	Sterile distilled water
Product concentrations for the assay	Pure (100%), 50% and 0.1%.
Aspect of the dilutions of the product	Pure (100%) and 50% blue transparent liquid; 0.1% transparent liquid.
Contact time	60 seconds
Assay temperature	20°C ± 1°C
Interfering substance	Bovine serum albumin 3 g/L plus erythrocytes 3 mL/L.
Stability of the mixture (interfering substance and product diluted in sterile hard water/distilled water)	Stable
Incubation temperature	+36°C ± 1°C
Identification of the strains used:	- *Mycobacterium avium* (ATCC 15769). - *Mycobacterium terrae* (CECT 3028 = ATCC 15755).

ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 16418/22/ROBCH

Results of the assay

- Controls and validation ..... See tables 1, 2, 3, 5, 6 and 7.
- Evaluation of mycobactericidal activity..... See table 4 and 8
- Number of replicates per assay organism .. 1.

Special remarks

- All controls and validation were between the basic limits.
- One concentration of the sample at least showed a log reduction less than 4 log.
- One concentration of the sample at least showed a log reduction higher than 4 log.

Conclusion

The product **Dezinfectant Universal "Bio-Dez"**, batch not indicated, when is pure (100%), **shows mycobactericidal activity** after 60 seconds at 20ºC under dirty conditions (bovine serum albumin 3 g/L and erythrocytes 3 mL/L), against the reference strains *Mycobacterium avium* (ATCC 15769) and *Mycobacterium terrae* (CECT 3028 = ATCC 15755), when tested as required by **UNE-EN 14563: 2009 Standard**.

Note: The results obtained correspond to the sample received in the laboratory.

Quality Assurance Review:

The assay development and the results obtained have been supervised by the Director of the study.

The Quality Assurance Director has inspected the development of the assay, proving that has been realized following the proper procedure and using the adequate media, materials and reagents, following the Good Laboratory Practices (GLPs) as well and the final report contains the primary data obtained.

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ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 16418/22/ROBCH

Results of the assay with *Mycobacterium avium* (ATCC 15769).

Time of dryness of carriers: 32 minutes (no longer than 60 minutes).

Seeding: Spread plate; No. of plates: 2/mL

Table 1.-Validation and controls

Suspension of validation (Nv_0)				Control of experimental conditions (A)				Control of the neutralizer (B)				Validation of the method (C) Sample concentration: Pure			
Counts per plate		Vc_1	Vc_2	Counts per plate		Vc_1	Vc_2	Counts per plate		Vc_1	Vc_2	Counts per plate		Vc_1	Vc_2
47 + 52	56 + 49	99	105	45 + 48	46 + 51	93	97	42 + 47	49 + 44	89	93	44 + 46	43 + 41	90	84
$30 \le X$ of $Nv_0 \le 160$? $X = 102$				X of A is $\ge 0.5 \times X$ de Nv_0? $X = 95$				X of B is $\ge 0.5 \times X$ of Nv_0? $X = 91$				X of C is $\ge 0.5 \times X$ of Nv_0? $X = 87$			
Yes				Yes				Yes				Yes			

Table 2.-Suspension of the assay

Suspension of assay (N)	N	Counts per plate		Vc_1	Vc_2	X_{wm} 4.45 x 10^9
	10^{-7}	223 + 214	230 + 222	437	452	lg N= 9.65 $9.17 \le \lg N \le 9.7$? Yes
	10^{-8}	21 + 23	24 + 23	44	47	

Table 3.-Water control

Water control (Nw)	Nw	Counts per plate		Vc_1	Vc_2	Xwm 8.2 x 10^7
	10^{-4}	>330 + >330	>330 + >330	>660	>660	lg Nw= 7.91 $6.15 \le \lg Nw \le \lg N - 1.3$? Yes
	10^{-5}	37 + 43	45 + 39	80	84	

Table 4.-Results of the activity assays with the sample

Sample concentration (%)	Dilution	Counts per plate		Vc_1	Vc_2	Lg Na = lg (X o Xwm)+1	Lg R (lgNw = 7.91)	Time of contact (sec)
Pure (100%)	10^0	0 + 0	0 + 0	< 14	< 14	< 2.15	>5.76	60
	10^{-1}	0 + 0	0 + 0	< 14	< 14			
	10^{-2}	0 + 0	0 + 0	< 14	< 14			
	10^{-3}	0 + 0	0 + 0	< 14	< 14			
50%	10^0	0 + 0	0 + 0	< 14	< 14	< 2.15	>5.76	60
	10^{-1}	0 + 0	0 + 0	< 14	< 14			
	10^{-2}	0 + 0	0 + 0	< 14	< 14			
	10^{-3}	0 + 0	0 + 0	< 14	< 14			
0.1%	10^0	>330+ >330	>330+ >330	>660	>660	>6.82	<1.09	60
	10^{-1}	>330+ >330	>330+ >330	>660	>660			
	10^{-2}	>330+ >330	>330+ >330	>660	>660			
	10^{-3}	>330+ >330	>330+ >330	>660	>660			

*Test method accredited # Test performed by subcontractor. Ø Non accredited methods.

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ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 16418/22/ROBCH

Results of the assay with *Mycobacterium terrae* (CECT 3028 = ATCC 15755).
Time of dryness of carriers: 29 minutes (no longer than 60 minutes).
Seeding: Spread plate; No. of plates: 2/mL

Table 5.-Validation and controls

Suspension of validation (Nv_0)				Control of experimental conditions (A)				Control of the neutralizer (B)				Validation of the method (C) Sample concentration: Pure			
Counts per plate		Vc_1	Vc_2	Counts per plate		Vc_1	Vc_2	Counts per plate		Vc_1	Vc_2	Counts per plate		Vc_1	Vc_2
49 + 54	50 + 48	103	98	41 + 44	44 + 48	85	92	43 + 37	45 + 41	80	86	39 + 43	38 + 39	82	77
$30 \le X$ of $Nv_0 \le 160$? $X = 100.5$				X of A is ≥ 0.5 x X de Nv_0? $X = 88.5$				X of B is ≥ 0.5 x X of Nv_0? $X = 83$				X of C is ≥ 0.5 x X of Nv_0? $X = 79.5$			
Yes				Yes				Yes				Yes			

Table 6.-Suspension of the assay

Suspension of assay (N)	N	Counts per plate		Vc_1	Vc_2	X_{wm} 3.91 x 10^9 lg N= 9.59 $9.17 \le \lg N \le 9.7$? Yes
	10^{-7}	207 + 193	187 + 199	400	386	
	10^{-8}	21 + 18	17 + 19	39	36	

Table 7.-Water control

Water control (Nw)	Nw	Counts per plate		Vc_1	Vc_2	Xwm 6.25 x 10^7 lg Nw= 7.80 $6.15 \le \lg Nw \le \lg N - 1.3$? Yes
	10^{-4}	>330 + >330	>330 + >330	>660	>660	
	10^{-5}	30 + 31	33 + 31	61	64	

Table 8.-Results of the activity assays with the sample

Sample concentration (%)	Dilution	Counts per plate		Vc_1	Vc_2	Lg Na = lg (X o Xwm)+1	Lg R (lgNw = 7.80)	Time of contact (sec)
Pure (100%)	10^0	0 + 0	0 + 0	< 14	< 14	< 2.15	>5.65	60
	10^{-1}	0 + 0	0 + 0	< 14	< 14			
	10^{-2}	0 + 0	0 + 0	< 14	< 14			
	10^{-3}	0 + 0	0 + 0	< 14	< 14			
50%	10^0	185 +172	190 + 179	357	369	4.56	3.24	60
	10^{-1}	15 + 17	18 + 16	32	34			
	10^{-2}	1 + 2	2 + 0	< 14	< 14			
	10^{-3}	0 + 0	0 + 0	< 14	< 14			
0.1%	10^0	>330+ >330	>330+ >330	>660	>660	>6.82	<0.98	60
	10^{-1}	>330+ >330	>330+ >330	>660	>660			
	10^{-2}	>330+ >330	>330+ >330	>660	>660			
	10^{-3}	>330+ >330	>330+ >330	>660	>660			

*Test method accredited # Test performed by subcontractor. Ø Non accredited methods.
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ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 16418/22/ROBCH

Explanations:
Vc = Count per mL (one or more plates).
X= mean of Vc_1 and Vc_2.
Xwm = Weighted mean of *X*;
R = reduction ($\lg R = \lg Nw - \lg Na$).
If $Na < 140$, $\lg R = > [\lg Nw - 2.15]$

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RAPORT DE INCERCARE NR. 34692/23/ROBCH

Client **ECOCHIM-GRUP SRL** STRADA PETRICANI 21/3 2059 CHIȘINĂU	Numărul eșantionului: **34692/23/ROBCH** Descriere obiect de incercat *(conform cu declaratia Clientului)* **Dezinfectant Universal "Bio-Dez"** **Lot: -** **Cantitate prelevata:500 ml** **Responsabil prelevare: Cristinov Alexandr** **Ora receptiei probei: 08:00** **Temperatura receptie proba: 15°C** **Sample condition with no objections**
Data primirii obiectului de incercat: **17.05.2023** Data inceperii incercarii: **26.05.2023** Data finalizarii incercarii: **07.11.2023** Data eliberarii raportului: **07.11.2023**	**Comanda din 17.05.2023** Probele au fost prelevate si livrate de catre Client.

Parametrii de testare	Metoda de testare	Unitate de masura	Rezultat
# * Quantitative suspension test for the evaluation of bactericidal activity in medical area	EN 13727:2012+A2:2015	-	Test method performed by the subcontractor; the results are taken in full from the test report No D/23/ B0419, issued by the subcontractor. The results of the analysis are listed starting with enclosure No1 to report of analysis.

Responsabil incercare: Mariana Ilinca, Sef Laborator Microbiologie
Validat de: Mariana Ilinca, Sef Laborator Microbiologie
Autorizat de: Alina-Roxana Mihai, General Manager *(Aprobat cu semnatura electronica)*

Laborator: Bucuresti 041914, sos. Berceni nr.8

* Metoda de testare acreditata # Test efectuat de catre subcontractor
ø Incercari neacreditate

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Autorizatie A.N.S.V.S.A. nr. 115 din 18.06.2018

ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 34692/23/ROBCH

A) IDENTYFICATION OF THE SAMPLE	
Name of the product/Details about the product	**Dezinfectant Universal "Bio-Dez".** Manufacturer(supplier): Ecochim-Grup Condition of use: Instrument disinfection, surface disinfection, Hygienic handrub, surgical handrub.
Active(s) Substance(s) and its concentration(s)	Ethyl alcool 72-76%, CAS 64-17-5 and CE 200-578-6 Benzalkonium chloride 0.024-0.029%, CAS 68424-85-1 and CE 270-325-2 Methylthionibium chloride 0.00024%, CAS 61-73-4 and 200-515-2.
Concentration ordered for the assay	97%, 80%.
B) TEST METHOD	
Performed in accredited subcontracted partner laboratory: Scope of Accreditation Nr. 648/LE1286 Report No.: D/23/B0419– Quantitative evaluation assay of the bactericidal activity in the medical area (phase 2, step 1), with the product "Dezinfectant Universal "Bio-Dez"". (EN 13727: 2012 + A2: 2015 Standard)	EN 13727: 2012 + A2: 2015. Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants for instruments used in Medicine. Test method and requirements (phase 2, step 1).
Testing method	EN 13727: 2012 + A2: 2015 Standard
Methods of assay and its validation UNE-EN 13727: 2012 + A2: 2015 Standard	
Method	Dilution-neutralization.
Neutralizer	Tryptone 5 g/L, yeast extract 2.5 g/L, dextrose 10 g/L, sodium thioglycolate 1 g/L, sodium thiosulfate 1 g/L, sodium bisulphite 2.5 g/L, soya lecithin 7 g/L, polysorbate-80 5 g/L, glycine 1 g/L, l-histidine 1 g/L and saponin 30 g/L.
C) INFORMATION ABOUT SAMPLE RECEPTION	
Date of reception of the sample	2023/05/18.
Date of reception of order with test conditions	2023/08/30.
Aspect of the received product	Blue liquid in plastic container.
D) EXPERIMENTAL CONDITIONS	
Assay period	2023/10/11 to 2023/10/15.
Solvent of the product used in the assay	Sterile distilled water.
Product concentrations for the assay	97%, 80%, 50% and 0.1%.
Aspect of the dilutions of the product	97%, 80% and 50% blue liquid; 0.1% transparent liquid..
Contact time	60 seconds.
Assay temperature	20°C ± 1°C
Interfering substance	Bovine serum albumin 3 g/L + erythrocytes 3 mL/L.
Stability of the mixture (interfering substance and product diluted in sterile distilled water)	97% flocs formation; 80%, 50% and 0.1% stable.
Incubation temperature	+36°C ± 1°C
Identification of the strains used:	– *Pseudomonas aeruginosa* CECT-116 (ATCC-15442). – *Staphylococcus aureus* CECT-239 (ATCC-6538). – *Enterococcus hirae* CECT-4081 (ATCC-10541). - *Escherichia coli* K12 (CECT 433 = NCTC 10538).

Results of the assay

-	Assay of validation	See tables 1, 2, 4, 5, 7, 8, 10, 11, 13, 14, 16, 17, 19, 20, 22 and 23.
-	Evaluation of bactericidal activity	See tables 3, 6, 9, 12, 15, 18, 21 and 24.
-	Number of replicates per assay organism.	1.

Special remarks

- All controls and validation were between the basic limits.
- For a valid test, at least one concentration must show a log reduction lower than 5 log, and at least one concentration must show a log reduction equal or higher than 5 log.
- Flocs formation is observed during the test procedure at 97%.
- The client requests the complete test including the concentration of 80% as the maximum concentration. It also requests the modified method (97%) additionally.

Conclusion

The product **Dezinfectant Universal "Bio-Dez"**, batch 34692/23/ROBCH, when it is pure (97%) (modified method) and 80%, concentrations requested by the client, **shows bactericidal activity** after 60 seconds at 20ºC ± 1ºC, under dirty conditions (bovine serum albumin 3 g/L and erythrocytes 3 mL/L), for the reference strains *Pseudomonas aeruginosa* (CECT 116 = ATCC 15442), *Staphylococcus aureus* (CECT 239 = ATCC 6538), *Enterococcus hirae* (CECT 4081 = ATCC 10541) and *Escherichia coli* K12 (CECT 433 = NCTC 10538), when tested according to **EN 13727: 2012 + A2: 2015 Standard.**

Note: The results obtained correspond to the sample received in the laboratory.

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ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 34692/23/ROBCH

Results of the assay (Bactericidal suspension) with *Pseudomonas aeruginosa* (CECT 116 = ATCC 15442).

Seeding: Pour plates. No. of plates: 1 /mL.

Table 1.-Validation and controls

Suspension of validation (*Nv*0)			**Control of experimental conditions (*A*)**			**Control of the neutralization (*B*)**			**Validation of the method (*C*) Sample concentration: 80%**		
*Vc*1	44	*X*= 42	*Vc*1	36	*X*= 35	*Vc*1	38	*X*= 37.5	*Vc*1	32	*X*= 33
*Vc*2	40		*Vc*2	34		*Vc*2	37		*Vc*2	34	
30 ≤ *X* of *Nv*0 ≤ 160? Yes			*X* of *A* is ≥ 0.5 *X* of *Nv*0? Yes			*X* of *B* is ≥ 0.5 *X* of *Nv*0? Yes			*X* of *C* is ≥ 0.5 *X* of *Nv*0? Yes		
Suspension of validation (*NvB*)			*Vc*1: 40 *Vc*2: 39			*X* = 39.5 30 ≤ x of *NvB*/1000 ≤ 160? Yes					

Table 2.-Suspension of the assay

Suspension of assay (*N* and *N*0)	*N*	*Vc*1	*Vc*2	*Xwm* = 1.68 x 10^8, lg *N* = 8.22 *N*0 = *N*/10; lg *N*0 = 7.22 7.17 ≤ lg *N*0 ≤ 7.70? Yes
	10^{-6}	164	171	
	10^{-7}	18	16	

Table 3.-Results of the activity assays with the sample

Concentrations of the sample (%)	Dilutions steps	*Vc*1	*Vc*2	Lg *Na* = lg (*X* x 10 o *Xwm* x 10)	Lg *R* (Lg *N*0=7.22)	Time of contact (sec)
80%	Na^0	<14	<14	<2.15	>5.07	60
	Na^{-1}	<14	<14			
50%	Na^0	<14	<14	<2.15	>5.07	60
	Na^{-1}	<14	<14			
0.1%	Na^0	>330	>330	>4.52	<2.70	60
	Na^{-1}	>330	>330			

Explanations:
Vc = number per mL (one or two plates); *Xwm* = weighted mean of *X*.
X = mean of *Vc*1 and *Vc*2 (duplicate of 1 + 2);
Logarithmic reduction *R*: (lg *R* = lg *N*0 – lg *Na*).

ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 34692/23/ROBCH

Results of the assay (Bactericidal suspension) with *Pseudomonas aeruginosa* (CECT 116 = ATCC 15442) following the modified method (97%).

Seeding: Pour plates. No. of plates: 1 /mL.

Table 4.-Validation and controls

Suspension of validation (*Nv0*)			**Control of experimental conditions (*A*)**			**Control of the neutralization (*B*)**			**Validation of the method (*C*) Sample concentration: 97%**		
Vc1	42	*X*= 41	*Vc1*	37	*X*= 36	*Vc1*	31	*X*= 32	*Vc1*	30	*X*= 31
Vc2	40		*Vc2*	35		*Vc2*	33		*Vc2*	32	
30 ≤ *X* of *Nv0* ≤ 160? Yes			*X* of *A* is ≥ 0.5 *X* of *Nv0*? Yes			*X* of *B* is ≥ 0.5 *X* of *Nv0*? Yes			*X* of *C* is ≥ 0.5 *X* of *Nv0*? Yes		
Suspension of validation (*NvB*)			*Vc1*: 43 *Vc2*: 45			*X* = 44 30 ≤ x of *NvB*/1000 ≤ 160? Yes					

Table 5.-Suspension of the assay

Suspension of assay (*N* and *N0*)	*N*	*Vc1*	*Vc2*	*Xwm* = 1.86 x 10^9, lg *N* = 9.27 *N0* = *N*/100; lg *N0* = 7.27 7.17 ≤ lg *N0* ≤ 7.70? Yes
	10^{-7}	189	183	
	10^{-8}	20	18	

Table 6.-Results of the activity assays with the sample

Concentrations of the sample (%)	Dilutions steps	*Vc1*	*Vc2*	Lg *Na* = lg (*X* x 10 o *Xwm* x 10)	Lg *R* (Lg *N0*=7.27)	Time of contact (sec)
97%	Na^0	<14	<14	<2.15	>5.12	60
	Na^{-1}	<14	<14			

Explanations:
Vc = number per mL (one or two plates); *Xwm* = weighted mean of *X*.
X = mean of *Vc1* and *Vc2* (duplicate of 1 + 2);
Logarithmic reduction *R*: (lg *R* = lg *N0* – lg *Na*).

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ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 34692/23/ROBCH

Results of the assay (Bactericidal suspension) with *Staphylococcus aureus* (CECT 239 = ATCC 6538).

Seeding: Pour plates. No. of plates: 1 /mL.

Table 7.-Validation and controls

Suspension of validation (*Nv*0)			**Control of experimental conditions (*A*)**			**Control of the neutralization (*B*)**			**Validation of the method (*C*) Sample concentration: 80%**		
Vc_1	48	X= 49	Vc_1	47	X= 46	Vc_1	48	X= 46	Vc_1	40	X= 42
Vc_2	50		Vc_2	45		Vc_2	44		Vc_2	44	
30 ≤ X of Nv_0 ≤ 160? Yes			X of A is ≥ 0.5 X of Nv_0? Yes			X of B is ≥ 0.5 X of Nv_0? Yes			X of C is ≥ 0.5 X of Nv_0? Yes		
Suspension of validation (Nv_B)			Vc_1: 52 Vc_2: 56			X = 54 30 ≤ x of Nv_B/1000 ≤ 160? Yes					

Table 8.-Suspension of the assay

Suspension of assay (N and N_0)	N	Vc_1	Vc_2	Xwm = 1.84 x 10^8, lg N = 8.27 N_0 = N/10; lg N_0 = 7.27 7.17 ≤ lg N_0 ≤ 7.70? Yes
	10^{-6}	177	189	
	10^{-7}	20	19	

Table 9.-Results of the activity assays with the sample

Concentrations of the sample (%)	Dilutions steps	Vc_1	Vc_2	Lg Na = lg (X x 10 o Xwm x 10)	Lg R (Lg N_0=7.27)	Time of contact (sec)
80%	Na^0	<14	<14	<2.15	>5.12	60
	Na^{-1}	<14	<14			
50%	Na^0	<14	<14	<2.15	>5.12	60
	Na^{-1}	<14	<14			
0.1%	Na^0	>330	>330	>4.52	<2.75	60
	Na^{-1}	>330	>330			

Explanations:
Vc = number per mL (one or two plates); Xwm = weighted mean of X.
X = mean of Vc_1 and Vc_2 (duplicate of 1 + 2);
Logarithmic reduction R: (lg R = lg N_0 – lg Na).

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ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 34692/23/ROBCH

Results of the assay (Bactericidal suspension) with *Staphylococcus aureus* (CECT 239 = ATCC 6538) following the modified method (97%).

Seeding: Pour plates. No. of plates: 1 /mL.

Table 10.-Validation and controls

Suspension of validation (*Nv0*)			**Control of experimental conditions (*A*)**			**Control of the neutralization (*B*)**			**Validation of the method (*C*) Sample concentration: 97%**		
Vc1	51	*X*= 52	*Vc1*	46	*X*= 48	*Vc1*	50	*X*= 52	*Vc1*	39	*X*= 40
Vc2	53		*Vc2*	50		*Vc2*	54		*Vc2*	41	
30 ≤ *X* of *Nv0* ≤ 160? Yes			*X* of *A* is ≥ 0.5 *X* of *Nv0*? Yes			*X* of *B* is ≥ 0.5 *X* of *Nv0*? Yes			*X* of *C* is ≥ 0.5 *X* of *Nv0*? Yes		
Suspension of validation (*NvB*)			*Vc1*: 56 *Vc2*: 58			*X* = 57 30 ≤ x of *NvB*/1000 ≤ 160? Yes					

Table 11.-Suspension of the assay

Suspension of assay (*N* and *N0*)	*N*	*Vc1*	*Vc2*	
	10^{-7}	190	201	*Xwm* = 1.97 x 10^9, lg *N* = 9.29 *N0* = *N*/100; lg *N0* = 7.29 7.17 ≤ lg *N0* ≤ 7.70? Yes
	10^{-8}	22	20	

Table 12.-Results of the activity assays with the sample

Concentrations of the sample (%)	Dilutions steps	*Vc1*	*Vc2*	Lg *Na* = lg (*X* x 10 o *Xwm* x 10)	Lg *R* (Lg *N0*=7.29)	Time of contact (sec)
97%	Na^0	<14	<14	<2.15	>5.14	60
	Na^{-1}	<14	<14			

Explanations:

Vc = number per mL (one or two plates); *Xwm* = weighted mean of *X*.

X = mean of *Vc1* and *Vc2* (duplicate of 1 + 2);

Logarithmic reduction *R*: (lg *R* = lg *N0* – lg *Na*).

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ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 34692/23/ROBCH

Results of the assay (Bactericidal suspension) with *Enterococcus hirae* (CECT 4081 = ATCC 10541).

Seeding: Pour plates. No. of plates: 1 /mL.

Table 13.-Validation and controls

Suspension of validation (*Nv*0)			**Control of experimental conditions (*A*)**			**Control of the neutralization (*B*)**			**Validation of the method (*C*) Sample concentration: 80%**		
Vc_1	47	X= 49	Vc_1	40	X=	Vc_1	47	X=	Vc_1	45	X= 44
Vc_2	51		Vc_2	44	42	Vc_2	42	44.5	Vc_2	43	
$30 \leq X$ of $Nv_0 \leq 160$? Yes			X of A is ≥ 0.5 X of Nv_0? Yes			X of B is ≥ 0.5 X of Nv_0? Yes			X of C is ≥ 0.5 X of Nv_0? Yes		
Suspension of validation (Nv_B)			Vc_1: 50 Vc_2: 52			X= 51 $30 \leq$ x of $Nv_B/1000 \leq 160$? Yes					

Table 14.-Suspension of the assay

	N	Vc_1	Vc_2	
Suspension of assay (N and N_0)	10^{-6}	181	192	$Xwm = 1.88 \times 10^8$, lg N = 8.27 $N_0 = N/10$; lg N_0 = 7.27 $7.17 \leq \lg N_0 \leq 7.70$? Yes
	10^{-7}	20	21	

Table 15.-Results of the activity assays with the sample

Concentrations of the sample (%)	Dilutions steps	Vc_1	Vc_2	Lg Na = lg (X x 10 o Xwm x 10)	Lg R (Lg N_0=7.27)	Time of contact (sec)
80%	Na^0	<14	<14	<2.15	>5.12	60
	Na^{-1}	<14	<14			
50%	Na^0	<14	<14	<2.15	>5.12	60
	Na^{-1}	<14	<14			
0.1%	Na^0	>330	>330	>4.52	<2.75	60
	Na^{-1}	>330	>330			

Explanations:
Vc = number per mL (one or two plates); Xwm = weighted mean of X.
X = mean of Vc_1 and Vc_2 (duplicate of 1 + 2);
Logarithmic reduction R: (lg R = lg N_0 – lg Na).

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Authorized by: Mariana Ilinca, Manager of Microbiological laboratory
Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 34692/23/ROBCH

Results of the assay (Bactericidal suspension) with *Enterococcus hirae* (CECT 4081 = ATCC 10541), following the modified method (97%).

Seeding: Pour plates. No. of plates: 1 /mL.

Table 16.-Validation and controls

Suspension of validation (Nv_0)			**Control of experimental conditions (A)**			**Control of the neutralization (B)**			**Validation of the method (C) Sample concentration: 97%**		
Vc_1	46	X= 47	Vc_1	40	X= 42	Vc_1	42	X= 44	Vc_1	37	X= 36
Vc_2	48		Vc_2	44		Vc_2	46		Vc_2	35	
$30 \leq X$ of $Nv_0 \leq 160$? Yes			X of A is ≥ 0.5 X of Nv_0? Yes			X of B is ≥ 0.5 X of Nv_0? Yes			X of C is ≥ 0.5 X of Nv_0? Yes		
Suspension of validation (Nv_B)			Vc_1: 51 Vc_2: 53			X= 52 $30 \leq$ x of $Nv_B/1000 \leq 160$? Yes					

Table 17.-Suspension of the assay

Suspension of assay (N and N_0)	N	Vc_1	Vc_2	$Xwm = 1.84 \times 10^9$, $\lg N = 9.27$ $N_0 = N/100$; $\lg N_0 = 7.27$ $7.17 \leq \lg N_0 \leq 7.70$? Yes
	10^{-7}	179	188	
	10^{-8}	20	18	

Table 18.-Results of the activity assays with the sample

Concentrations of the sample (%)	Dilutions steps	Vc_1	Vc_2	Lg Na = lg (X x 10 o Xwm x 10)	Lg R (Lg N_0=7.27)	Time of contact (sec)
97%	Na^0	<14	<14	<2.15	>5.12	60
	Na^{-1}	<14	<14			

Explanations:
Vc = number per mL (one or two plates); Xwm = weighted mean of X.
X = mean of Vc_1 and Vc_2 (duplicate of 1 + 2);
Logarithmic reduction R: ($\lg R = \lg N_0 - \lg Na$).

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ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 34692/23/ROBCH

Results of the assay (Bactericidal suspension) with *Escherichia coli* K12 (CECT 433 = NCTC 10538).

Seeding: Pour plates. No. of plates: 1 /mL.

Table 19.-Validation and controls

Suspension of validation (*Nv*0)			**Control of experimental conditions (*A*)**			**Control of the neutralization (*B*)**			**Validation of the method (*C*) Sample concentration: 80%**		
*Vc*1	47	*X*= 46	*Vc*1	40	*X*= 39.5	*Vc*1	39	*X*= 38	*Vc*1	41	*X*= 42
*Vc*2	45		*Vc*2	39		*Vc*2	37		*Vc*2	43	
30 ≤ *X* of *Nv*0 ≤ 160? Yes			*X* of *A* is ≥ 0.5 *X* of *Nv*0? Yes			*X* of *B* is ≥ 0.5 *X* of *Nv*0? Yes			*X* of *C* is ≥ 0.5 *X* of *Nv*0? Yes		
Suspension of validation (*NvB*)			*Vc*1: 45 *Vc*2: 41			*X*= 43 30 ≤ x of *NvB*/1000 ≤ 160? Yes					

Table 20.-Suspension of the assay

	N	*Vc*1	*Vc*2	
Suspension of assay (*N* and *N*0)	10^{-6}	168	175	*Xwm* = 1.72 x 10^8, lg *N* = 8.24 *N*0 = *N*/10; lg *N*0 = 7.24 7.17 ≤ lg *N*0 ≤ 7.70? Yes
	10^{-7}	19	17	

Table 21.-Results of the activity assays with the sample

Concentrations of the sample (%)	Dilutions steps	*Vc*1	*Vc*2	Lg *Na* = lg (*X* x 10 o *Xwm* x 10)	Lg *R* (Lg *N*0=7.24)	Time of contact (sec)
80%	Na^0	<14	<14	<2.15	>5.09	60
	Na^{-1}	<14	<14			
50%	Na^0	<14	<14	<2.15	>5.09	60
	Na^{-1}	<14	<14			
0.1%	Na^0	>330	>330	>4.52	<2.72	60
	Na^{-1}	>330	>330			

Explanations:
Vc = number per mL (one or two plates); *Xwm* = weighted mean of *X*.
X = mean of *Vc*1 and *Vc*2 (duplicate of 1 + 2);
Logarithmic reduction *R*: (lg *R* = lg *N*0 – lg *Na*).

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Date: 07.11.2023
Authorized by: Mariana Ilinca, Manager of Microbiological laboratory
Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 34692/23/ROBCH

Results of the assay (Bactericidal suspension) with *Escherichia coli* K12 (CECT 433 = NCTC 10538), following the modified method (97%).

Seeding: Pour plates. No. of plates: 1 /mL.

Table 22.-Validation and controls

Suspension of validation (Nv_0)			**Control of experimental conditions (*A*)**			**Control of the neutralization (*B*)**			**Validation of the method (*C*) Sample concentration: 97%**		
Vc_1	42	X= 43	Vc_1	36	X= 37.5	Vc_1	33	X= 34.5	Vc_1	37	X= 36
Vc_2	44		Vc_2	39		Vc_2	36		Vc_2	35	
$30 \leq X$ of $Nv_0 \leq 160$? Yes			X of A is ≥ 0.5 X of Nv_0? Yes			X of B is ≥ 0.5 X of Nv_0? Yes			X of C is ≥ 0.5 X of Nv_0? Yes		
Suspension of validation (Nv_B)			Vc_1: 40 Vc_2: 39			X = 39.5 $30 \leq$ x of $Nv_B/1000 \leq 160$? Yes					

Table 23.-Suspension of the assay

	N	Vc_1	Vc_2	
Suspension of assay (N and N_0)	10^{-7}	180	165	$Xwm = 1.74 \times 10^9$, lg N = 9.24 $N_0 = N/100$; lg N_0 = 7.24 $7.17 \leq \lg N_0 \leq 7.70$? Yes
	10^{-8}	19	18	

Table 24.-Results of the activity assays with the sample

Concentrations of the sample (%)	Dilutions steps	Vc_1	Vc_2	Lg Na = lg (X x 10 o Xwm x 10)	Lg R (Lg N_0=7.24)	Time of contact (sec)
97%	Na^0	<14	<14	<2.15	>5.09	60
	Na^{-1}	<14	<14			

Explanations:
Vc = number per mL (one or two plates); Xwm = weighted mean of X.
X = mean of Vc_1 and Vc_2 (duplicate of 1 + 2);
Logarithmic reduction R: (lg R = lg N_0 – lg Na).

JS. HAMILTON ROMANIA S.R.L.
8 Berceni Street, 041902 Bucharest, Romania
Tel.+40 21 634 10 81 bucharest@hamilton.com.pl, www.hamilton.com.pl

Date: 07.11.2023
Authorized by: Mariana Ilinca, Manager of Microbiological laboratory
Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

TEST REPORT No. 455216/23/INT

Client: **"ECOCHIM-GRUP" S.R.L. str. Nationala, or. Ungheni, Republica Moldova**		Description of the sample *(as per Client's declaration)*
Sample reception date:	24.08.2023	Dezinfectant Universal "Bio-Dez" Lot/Batch: - Production date: 05.08.2023 Expiration date: 05.08.2026 Sampling date: 23.08.2023 Sampling quantity: 1x 200ml Sample temperature: 17°C Reception hour: 12:30 Responsible for sampling: Crestinov Alexandr Sample condition with no objections
Test report date:	08.09.2023	

Dermatological test - Open test (25 subjects with allergological history, 25 subjects, without allergological history)

Prepared by: Natalia Dawidowicz, Technician
Authorized by: Karolina Osiecka (2487308), Dermatologist - venereologist
Paulina Maciszka, Project Manager (qualified electronic signature)

Laboratory: ul. Bajana 3D, 80-463 Gdańsk

TEST REPORT No. 455216/23/INT

THE STUDY IS COMPLIANT WITH:

Regulation of the European Parliament and of the Council (EC) No. 1223/2009 of 30 November 2009 on Cosmetic Products
Cosmetics Europe The Personal Care Association (previously COLIPA) Guidelines Product Test Guidelines for the Assessment of Human Skin Compatibility 1997
Cosmetics Europe The Personal Care Association (previously COLIPA) Guidelines for the Evaluation of the Efficacy of Cosmetic Products 2008

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LIST OF CONTENTS

Prepared by: Natalia Dawidowicz, Technician
Authorized by: Karolina Osiecka (2487308), Dermatologist - venereologist
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Laboratory: ul. Bajana 3D, 80-463 Gdańsk

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1. BASIS OF THE STUDY

- Samples delivered by the Sponsor.
- The qualitative composition of the product delivered by the Sponsor.
- The results of microbiological purity of the product provided by the Sponsor (or declaration from the Sponsor about microbiological purity).

The Sponsor is responsible for conformity with the declared quality composition of the product as well as for the microbiological purity test of the delivered samples.

2. OBJECT OF THE STUDY

Parameter	Description
Appearance	Liquid
Colour	Blue
Fragrance	Characteristic for raw materials (or fragrance composition)
Packaging	Replacement packaging containing the name and sample number for testing

3. QUALITATIVE COMPOSITION OF THE PRODUCT

The qualitative composition was delivered to the Laboratory by the Sponsor before the start of the study.

4. PURPOSE OF THE STUDY

The purpose of the study was to assess irritating properties (skin tolerance) of the product on a healthy adult skin, with applied patch test.

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5. DESCRIPTION OF STUDY SUBJECTS

The study subjects (25 people) were healthy, with negative history of allergy. General inclusion criteria for the selection of study subjects were the following: healthy men and women over 18 years old, phototype: I-IV on Fitzpatrick scale, Caucasians, skin without irritations and changes requiring pharmacological treatment. General exclusion criteria were the following: volunteers who at the time used any treatment on the skin area subject to the study, volunteers exhibiting or having a known history of acute or chronic dermatological, medical and/or physical conditions that could influence the outcome of the study, pregnant or breastfeeding women or women planning a pregnancy during the study. None of the study subjects reported documented oversensitivity or history of adverse reactions to individual ingredients of the product tested. All the study subjects fulfilled the requirements of inclusion for tests and signed the Informed Consent Form (ICF). Additionally, they were informed on the purpose, methodology of the study and possible adverse effects. The skin at the application area (arms or interscapular area) was healthy, without lesions. The study subjects were advised to exercise caution in handling the applied contact tests.

6. TESTING METHODOLOGY

The preparation in the appropriate concentration was applied onto to the skin on the forearm in the area of 3x3 cm. The reading of skin response was performed 15 minutes, 30 minutes, 1 hour, and 24 hours after the test application. Simultaneously, to assure the objectivity of the results of the study and in order to exclude possible reading errors connected with dermal irritations one sample control (control sample with water) was carried out. The results of the study are presented in section 10 of this report. If irritations appeared or persisted 24h after the application, an additional examination took place after 48 hours. Determining the response of the skin, the dermatologist assessed the irritating and sensitising effects of the tested product. The study results might have been influenced by factors such as lifestyle, stress, diet and environmental conditions, etc.

7. DATE OF THE STUDY

05.09.2023 – 08.09.2023

Prepared by: Natalia Dawidowicz, Technician
Authorized by: Karolina Osiecka (2487308), Dermatologist - venereologist
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8. EVALUATION PARAMETERS

EVALUATION PARAMETERS OF SKIN REACTION	
Erythema	**Classification point**
No erythema	0
Light erythema	0.5
Erythema and/or papules	1
Erythema and/or papules and/or vesicles	2
Erythema and/or papules and/or vesicles and/or blisters	3
Erythema Bullous and/or ulcerative reaction and/or papules and/or vesicles and/or blisters	4
Edema	**Classification point**
No edema	0
Very light edema (hardly visible)	1
Light edema	2
Moderate edema (about 1mm raised skin)	3
Strong edema (extended swelling even beyond the application area)	4

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9. RESULTS

9.1. CHARACTERISTICS OF VOLUNTEERS

Table 1

No. of subject	Identification of subject	Begining of the study	Age	Sex	Phototype
1	CHY.AG	05.09.2023	26	F	II
2	DAW.NA	05.09.2023	24	F	II
3	BIE.IZ	05.09.2023	34	F	II
4	KOC.KR	05.09.2023	54	M	II
5	KRZ.EW	05.09.2023	37	F	II
6	ZAM.PA	05.09.2023	32	F	II
7	JAG.KR	05.09.2023	32	M	II
8	URB.BA	05.09.2023	65	F	II
9	TRE.MI	05.09.2023	57	F	II
10	BOC.AL	05.09.2023	44	F	II
11	FLI.AN	05.09.2023	35	F	II
12	PAC.NA	05.09.2023	24	F	II
13	KIE.MA	05.09.2023	26	F	II
14	ZAW.AG	05.09.2023	41	F	II
15	FUS.MO	05.09.2023	28	F	II
16	MAM.AG	05.09.2023	24	F	II
17	WEN.MO	05.09.2023	25	F	II
18	WOD.KA	05.09.2023	34	F	II
19	KOS.DO	05.09.2023	23	F	II
20	NOW.AR	05.09.2023	51	M	II
21	SEP.JA	05.09.2023	42	M	II
22	PIS.PI	05.09.2023	46	M	II
23	JER.DA	05.09.2023	56	F	II
24	MUS.NA	05.09.2023	37	F	II
25	BEC.EL	05.09.2023	58	F	II
		Min	23	**No. F**	**phototype I**
		Max	65	20	0
		Average	38	**No. M**	**phototype II**
				5	25
					phototype III
					0
					phototype IV
					0

Table 1. Characteristics of volunteers with a negative history of allergy

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Table 2

No. of subject	Identification of subject	Begining of the study	Age	Sex	Phototype
1	CIE.MA	05.09.2023	62	F	II
2	SZY.UR	05.09.2023	37	F	II
3	TRO.MA	05.09.2023	44	F	II
4	SKU.IW	05.09.2023	45	F	II
5	SZY.MA	05.09.2023	51	F	II
6	ARB.YU	05.09.2023	22	F	II
7	KOR.DO	05.09.2023	48	F	II
8	GAN.MA	05.09.2023	59	F	II
9	TAR.AG	05.09.2023	58	F	II
10	RAT.EM	05.09.2023	38	F	II
11	PIO.EL	05.09.2023	53	F	II
12	KWI.BO	05.09.2023	68	F	II
13	WYS.BE	05.09.2023	35	F	II
14	ARB.AL	05.09.2023	22	F	II
15	ARB.LU	05.09.2023	45	F	II
16	ZAL.IZ	05.09.2023	44	F	II
17	SLE.AG	05.09.2023	45	F	II
18	GOR.AG	05.09.2023	22	F	II
19	WAN.SY	05.09.2023	25	F	II
20	SZE.KA	05.09.2023	22	F	II
21	HIR.HA	05.09.2023	47	F	II
22	RAD.MA	05.09.2023	57	F	II
23	MAN.MA	05.09.2023	48	F	II
24	HAN.AN	05.09.2023	23	F	II
25	ROZ.AG	05.09.2023	41	F	II
		Min	22	**No. F**	**phototype I**
		Max	68	25	0
		Average	42	**No. M**	**phototype II**
				0	25
					phototype III
					0
					phototype IV
					0

Table 2. Characteristics of volunteers with a positive history of allergy

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9.2. TABLE OF SKIN RESPONSE

Table 3

No.	Evaluation after 15 minutes of product application		Evaluation after 30 minutes of product application		Evaluation after 1 hour of product application		Evaluation after 24 hours of product application		Evaluation after 48 hours of product application	
	Erythema	Edema	Erythema	Edema	Erythema	Edema	Erythema	Edema	Erythema	Edema
1	0	0	0	0	0	0	0	0	Examination skipped	
2	0	0	0	0	0	0	0	0	Examination skipped	
3	0	0	0	0	0	0	0	0	Examination skipped	
4	0	0	0	0	0	0	0	0	Examination skipped	
5	0	0	0	0	0	0	0	0	Examination skipped	
6	0	0	0	0	0	0	0	0	Examination skipped	
7	0	0	0	0	0	0	0	0	Examination skipped	
8	0	0	0	0	0	0	0	0	Examination skipped	
9	0	0	0	0	0	0	0	0	Examination skipped	
10	0	0	0	0	0	0	0	0	Examination skipped	
11	0	0	0	0	0	0	0	0	Examination skipped	
12	0	0	0	0	0	0	0	0	Examination skipped	
13	0	0	0	0	0	0	0	0	Examination skipped	
14	0	0	0	0	0	0	0	0	Examination skipped	
15	0	0	0	0	0	0	0	0	Examination skipped	
16	0	0	0	0	0	0	0	0	Examination skipped	
17	0	0	0	0	0	0	0	0	Examination skipped	
18	0	0	0	0	0	0	0	0	Examination skipped	
19	0	0	0	0	0	0	0	0	Examination skipped	
20	0	0	0	0	0	0	0	0	Examination skipped	
21	0	0	0	0	0	0	0	0	Examination skipped	
22	0	0	0	0	0	0	0	0	Examination skipped	
23	0	0	0	0	0	0	0	0	Examination skipped	
24	0	0	0	0	0	0	0	0	Examination skipped	
25	0	0	0	0	0	0	0	0	Examination skipped	

Table 3. Results for volunteers with a negative history of allergy

Prepared by: Natalia Dawidowicz, Technician
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Table 4

No.	Evaluation after 15 minutes of product application		Evaluation after 30 minutes of product application		Evaluation after 1 hour of product application		Evaluation after 24 hours of product application		Evaluation after 48 hours of product application	
	Erythema	Edema	Erythema	Edema	Erythema	Edema	Erythema	Edema	Erythema	Edema
1	0	0	0	0	0	0	0	0	Examination skipped	
2	0	0	0	0	0	0	0	0	Examination skipped	
3	0	0	0	0	0	0	0	0	Examination skipped	
4	0	0	0	0	0	0	0	0	Examination skipped	
5	0	0	0	0	0	0	0	0	Examination skipped	
6	0	0	0	0	0	0	0	0	Examination skipped	
7	0	0	0	0	0	0	0	0	Examination skipped	
8	0	0	0	0	0	0	0	0	Examination skipped	
9	0	0	0	0	0	0	0	0	Examination skipped	
10	0	0	0	0	0	0	0	0	Examination skipped	
11	0	0	0	0	0	0	0	0	Examination skipped	
12	0	0	0	0	0	0	0	0	Examination skipped	
13	0	0	0	0	0	0	0	0	Examination skipped	
14	0	0	0	0	0	0	0	0	Examination skipped	
15	0	0	0	0	0	0	0	0	Examination skipped	
16	0	0	0	0	0	0	0	0	Examination skipped	
17	0	0	0	0	0	0	0	0	Examination skipped	
18	0	0	0	0	0	0	0	0	Examination skipped	
19	0	0	0	0	0	0	0	0	Examination skipped	
20	0	0	0	0	0	0	0	0	Examination skipped	
21	0	0	0	0	0	0	0	0	Examination skipped	
22	0	0	0	0	0	0	0	0	Examination skipped	
23	0	0	0	0	0	0	0	0	Examination skipped	
24	0	0	0	0	0	0	0	0	Examination skipped	
25	0	0	0	0	0	0	0	0	Examination skipped	

Table 4. Results for volunteers with a positive history of allergy

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10. CALCULATED VALUES

The following calculated values present the sum of negative reaction (erythema and edema) defined as Average Irritation Index (X_{av}).

	Evaluation after 15 minutes of product application	Evaluation after 30 minutes of product application	Evaluation after 1 hour of product application	Evaluation after 24 hours of product application	Evaluation after 48 hours of product application
The sum of negative reaction (the sum of classification points)	0,00	0,00	0,00	0,00	Examination skipped
X_{av}	0,00				

11. INTERPRETATION

The average irritation index (X_{av}) was calculated. The product was then classified according to the following table:

Average irritation index (xav)	Class
$\mathbf{X_{av}} < 0.50$	Not irritating
$0.50 \leq \mathbf{X_{av}} < 2.00$	Slightly irritating
$2.00 \leq \mathbf{X_{av}} < 5.00$	Moderately irritating
$5.00 \leq \mathbf{X_{av}}$	Highly irritating

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12. CONCLUSION

The patch test study was performed under dermatological control on a group of 25 volunteers. The study allowed the investigators to conclude that product Dezinfectant Universal "Bio-Dez" used by volunteers that didn't report documented oversensitivity or a history of adverse reactions to individual ingredients of the tested product, was well tolerated by the skin. In the tested group of volunteers there were no irritations or allergic reactions. The product meets the requirements of compatibility test with the skin (Skin Compatibility Test) and can be classified as NOT IRRITATING.

Prepared by: Natalia Dawidowicz, Technician
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13. SIGNATURES

Technician	**Natalia Dawidowicz**	
Dermatologist - venereologist	**Karolina Osiecka (2487308)**	
Project Manager	**Paulina Maciszka**	

*The Sponsor is responsible for conformity with the declared quality composition as well as microbiological purity of the delivered samples.
Attention: The released opinion of dermatological compatibility does not apply to people who are allergic to any ingredient of the tested product.

Prepared by: Natalia Dawidowicz, Technician
Authorized by: Karolina Osiecka (2487308), Dermatologist - venereologist
Paulina Maciszka, Project Manager (qualified electronic signature)

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Test with the certificate of GLPs
(Good Laboratory Practices)
No. 2/21-C.VAL. General Directorate of
Pharmacy and Medical Devices of the Health
Department of the Valencian Region. Spain

Mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants (phase 2, step 1), with the product "Dezinfectant Universal "Bio-Dez"". (EN 14348: 2005 Standard)

Report
Registration No.: D/23/B0672.

1. **Laboratory identification** ……...……. Instituto Valenciano de Microbiología.

2. **Client identification** ……... J.S. HAMILTON ROMANIA SRL.
   Address ……... SOS BERCENI, NR 8, SECTOR 4 BUCURESTI, ROMANIA, 041914.

3. **Sample identification** (information provided by the client)

- Product name ……..... **Dezinfectant Universal "Bio-Dez".**
- Batch number ……... 60363/23/ROBCH.
- Expiration date ……. 05.08.2026.
- Manufacturer/Supplier …….. SRL "Ecochim-Grup".
- Keeping conditions …… Not indicated.
- Condition for use ……..….. Hygienic handrub, Instrument disinfection, surface disinfection.
- Diluent recommended by the manufacturer ... Not indicated.
- Active compound/s and its concentration/s ... Ethyl alcool 72-76%, CAS 64-17-5 and CE 200-578-6 Benzalkonium chloride 0.024-0.029%, CAS 68424-85-1 and CE 270-325-2 Methylthionibium chloride 0.00024%, CAS 61-73-4 and 200-515-2.
- Concentrations requested for the assay ……. 80%

IVAMI is not responsible for client-supplied information. This information **is not covered** by the ENAC accreditation.

4. Information about sample reception

- Date of reception of the sample ……. 2023/08/31.
- Date of reception of order with test conditions …… 2023/08/25.
- Aspect of the received samples…… Purple transparent liquid in plastic package.

5. Method of assay and its validation (EN 14348: 2005 Standard)

- Method used ……. Dilution-neutralization.
- Neutralizer ……... Tryptone 5 g/L, yeast extract 2.5 g/L, dextrose 10 g/L, sodium thioglycolate 1 g/L, sodium thiosulfate 1g/L, sodium bisulphite 2.5 g/L, soya lecithin 7 g/L, polisorbate-80 5 g/L, glycine 1 g/L, l-histidine 1 g/L and saponin 30 g/L.

6. Experimental conditions

- Assay period (including prior preparation of the strains) ……. 2023/09/28 to 2023/11/09.
- Solvent of the product used in the assay ... Sterile distilled water.
- Product concentrations for the assay ……. 80%, 50% and 0.1%.
- Aspect of the dilutions of the product ….. 80% purple transparent liquid; 50% blue transparent liquid; 0.1% transparent liquid.
- Contact time …….. 60 seconds.
- Assay temperature ……. 20ºC ± 1ºC.
- Interfering substance ……. Bovine serum albumin 3 g/L and erythrocytes 3 mL/L.
- Stability of the mixture (interfering substance and product diluted in sterile distilled water) ……... Stable.
- Temperature of incubation …… 36ºC ± 1ºC.
- Identification of the strains used ..……

  – *Mycobacterium avium* (ATCC 15769).
  – *Mycobacterium terrae* (CECT 3028 = ATCC 15755).

7. Results of the assay

- Control and validation assays ……. See tables 1, 2, 4 and 5.
- Evaluation of mycobactericidal activity See tables 3 and 6.
- Number of replicates for each assay microorganism ……. 1.

8. Special remarks

- All controls and validation were between the basic limits.
- For a valid test, at least one concentration must show a reduction lower than 4 log and at least one concentration must show a reduction equal or higher than 4 log.
- The highest concentration that can be assayed in the test (80%) is due to the mixtures to perform the assay.

9. Conclusion

The product **Dezinfectant Universal "Bio-Dez",** batch 60363/23/ROBCH, when it is pure (80%), concentration requested by the client, **shows mycobactericidal activity** after 60 seconds, at 20ºC ± 1ºC, under dirty conditions (bovine serum albumin 3 g/L and erythrocytes 3 mL/L), against the strains *Mycobacterium avium* (ATCC 15769) and *Mycobacterium terrae* (CECT 3028 = ATCC 15755), when tested as required by **EN 14348: 2005 Standard**.

Note: The results obtained correspond to the sample received in the laboratory.

Use of the ENAC mark: The ENAC "*mark*" can only be used by the holder of the accreditation. Its use in packaging, installations, shop windows, advertising or other documentation format other than that issued by the accredited entity (IVAMI) is not allowed.

Bétera (Valencia), November 9, 2023.

MIGUEL FRANCO,
CLAUDIA (FIRMA)

Signed: Claudia Miguel.
Responsible Technician

Quality Assurance Review:

The assay development and the results obtained have been supervised by the Director of the study.

The Quality Assurance Director has inspected the development of the assay, proving that has been realized following the proper procedure and using the adequate media, materials and reagents, following as well the Good Laboratory Practices (GLPs) and the final report contains the primary data obtained.

MONTOYA VIECO, ELENA (FIRMA)

Signed. Elena Montoya.
Responsible for the Laboratory Area
(Study Director)

ESTEBAN BERMUDEZ, ENCARNACION PILAR (FIRMA)

Signed. Encarnación Esteban.
Technical Director
(Quality Assurance Director)

Reference

- **EN 14348: 2005**. Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants. Test methods and requirements (phase 2, step 1).

Table 1.-Assay with *Mycobacterium avium* (ATCC 15769): Validation and controls.

Suspension of validation (Nv_0)			**Control of experimental conditions (A)**			**Neutralizer (B)**			**Validation of the method (C) with sample concentration: 80%**		
Vc_1	97	X =	Vc_1	98	X = 96	Vc_1	92	X = 95	Vc_1	93	X = 91
Vc_2	104	100.5	Vc_2	94		Vc_2	98		Vc_2	89	
30 ≤ X of Nv_0 ≤ 160? Yes			X of A is ≥ 0.5 x X of Nv_0? Yes			X of B is ≥ 0.5 x X of Nv_0? Yes			X of C is ≥ 0.5 x X of Nv_0? Yes		

Table 2.- Assay with *Mycobacterium avium* (ATCC 15769): Suspension of the assay.

Suspension of the assay (N y N_0)	N	Vc_1	Vc_2	
	10^{-7}	391	405	Xwm = 4.00 x 10^9= lg = 9.60 N_0 = N/10 = lg = 8.60 8.17 ≤ N_0 ≤ 8.70? Yes
	10^{-8}	44	41	

Table 3.- Assay with *Mycobacterium avium* (ATCC 15769).

Concentrations of the sample (%)	**Dilutions**	Vc_1	Vc_2	**Lg Na = lg (X x 10 o Xwm x 10)**	**LgR (lgN_0 = 8.60)**	**Time of contact (sec)**
80 %	10^0	<14	<14	< 2.15	> 6.45	60
	10^{-1}	<14	<14			
	10^{-2}	<14	<14			
	10^{-3}	<14	<14			
50 %	10^0	<14	<14	< 2.15	> 6.45	60
	10^{-1}	<14	<14			
	10^{-2}	<14	<14			
	10^{-3}	<14	<14			
0.1 %	10^0	>660	>660	>6.82	<1.78	60
	10^{-1}	>660	>660			
	10^{-2}	>660	>660			
	10^{-3}	>660	>660			

Observations:

N 10^{-7}: 198 + 193; 202 + 203;
10^{-8}: 20 + 24; 19 + 22;
Na 80% 10^0: 0 + 0; 0 + 0;
50% 10^0: 0 + 0; 0 + 0;
0.1% 10^{-3}: >330 + >330; >330 + >330;

***Nv*$_0$**: 50 + 47; 55 + 49;
A: 46 + 52; 49 + 45;
B: 45 + 47; 49 + 49;
C: 48 + 45; 42 + 47;

Table 4.-Assay with *Mycobacterium terrae* (CECT 3028 = ATCC 15755): Validation and controls.

Suspension of validation (Nv_0)			**Control of experimental conditions (*A*)**			**Neutralizer (*B*)**			**Validation of the method (*C*) with sample concentration: 80%**		
Vc_1	79	X =	Vc_1	66	X = 68	Vc_1	75	X = 77	Vc_1	67	X =
Vc_2	82	80.5	Vc_2	70		Vc_2	79		Vc_2	72	69.5
30 ≤ X of Nv_0 ≤ 160? Yes			X of A is ≥ 0.5 x X of Nv_0? Yes			X of B is ≥ 0.5 x X of Nv_0? Yes			X of C is ≥ 0.5 x X of Nv_0? Yes		

Table 5.- Assay with *Mycobacterium terrae* (CECT 3028 = ATCC 15755): Suspension of the assay.

Suspension of the assay (N y N_0)	N	Vc_1	Vc_2	
	10^{-7}	295	275	Xwm = 2.86 x 10^9= lg = 9.46 N_0 = N/10 = lg = 8.46 8.17 ≤ N_0 ≤ 8.70? Yes
	10^{-8}	32	29	

Table 6.- Assay with *Mycobacterium terrae* (CECT 3028 = ATCC 15755).

Concentrations of the sample (%)	**Dilutions**	Vc_1	Vc_2	**Lg Na = lg (X x 10 o Xwm x 10)**	**LgR (lgN_0 = 8.46)**	**Time of contact (sec)**
80 %	10^0	<14	<14	<2.15	>6.31	60
	10^{-1}	<14	<14			
	10^{-2}	<14	<14			
	10^{-3}	<14	<14			
50 %	10^0	<14	<14	<2.15	>6.31	60
	10^{-1}	<14	<14			
	10^{-2}	<14	<14			
	10^{-3}	<14	<14			
0.1%	10^0	>660	>660	>6.82	<1.64	60
	10^{-1}	>660	>660			
	10^{-2}	>660	>660			
	10^{-3}	>660	>660			

Observations:

N 10^{-7}: 150 + 145; 130 + 145;
10^{-8}: 17 + 15; 14 + 15;

Na 80% 10^0: 0 + 0; 0 + 0;
50% 10^0: 0 + 0; 0 + 0;
0.1% 10^{-3}: >330 + >330; >330 + >330;

Nv_0: 40 + 39; 40 + 42;
A: 32 + 34; 34 + 36;
B: 39 + 36; 40 + 39;
C: 36 + 31; 35 + 37;

Explanations:
Vc**:** Counts per mL.
Xwm**:** weighted mean of X.
X**:** Values of Vc_1 and Vc_2 (1. + 2. duplicates); R**:** reduction (LgR = lgN_0 – lgNa).